

HEPATITIS C VIRAL SCREENING IN THE PRIMARY CARE SETTING

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Doctor of Nursing Practice Project  
Presented to the Faculty of Sinclair School of Nursing  
Graduate Studies  
University of Missouri

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In Partial Fulfillment  
of the Requirements for the Degree  
Doctor of Nursing Practice  
by  
LAUREN HIGHTOWER, BSN

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### Background and Significance

In the U.S., it is estimated that 4.1 million people were or are currently infected with the Hepatitis C virus according to the United States Preventive Services Task Force (USPTF) (2020). The Centers for Disease Control and Prevention (CDC) supports that since 2013 the incidence rate of acute Hepatitis C virus (HCV) has increased by 124% (2022). Disabled patients infected with HCV accrue a mean annual total of \$17,879 in additional healthcare costs in comparison to patients without HCV infection (Roebuck & Liberman, 2019). The annual cost of untreated HCV will peak in 2024 at \$9.1 billion (Razavi et al., 2013). Medicaid-filed claims are projected to save \$1.1 billion annually through the screening and treatment of HCV (Roebuck & Liberman, 2019).

The HCV universal screening endorsed by the USPSTF is a grade B recommendation for all adults 18 to 79 years of age or those with high-risk profiles outside the recommended age range (USPSTF, 2020). In 2023, an addendum to the recommendation was added to include adults of any age (CDC, 2023). Primary care clinicians have adopted the recommendation to implement universal screenings and treat identified infections of HCV. The World Health Organization (WHO) aims to reduce Hepatitis C viral infection by 90% and deaths due to HCV by 65% between 2020 and 2030 (WHO, 2022). Because HCV-infected individuals do not reliably show symptoms before disease complications have occurred, early identification is key in providing preventative and life-saving treatment (Li & Lo, 2015). With the advances in HCV treatment efficiency and decreased antiviral cost, viral elimination has been discussed as a potential outcome within the next decade (Lazarus et al., 2017; Graham & Trooskin, 2020).

### Statement of Purpose and PICOT

This quality improvement project aims to implement an evidence-based protocol using an educational session to increase hepatitis C screening in the primary care setting following the 2020 USPSTF recommendations for universal HCV infection screenings for all adults 18-99 years who have not been previously tested for HCV, regardless of high-risk behaviors. In adults aged 18-99 years, being seen by a primary care provider (*P*) how does universal screening as recommended by the USPSTF for hepatitis C virus (*I*) compared to the current screening processes (*C*) affect screening orders for HCV-Ab, confirmatory diagnostic HCV-RNA testing on HCV-Ab positives, and patient referral for HCV-RNA treatment (*O*) within a three-month time frame (*T*)?

The objectives of the project are:

1. A 5% increase in HCV screening using HCV reflex testing in the target population, after an education intervention, will be demonstrated within a 3-month period.
2. A 5% increase in patient referrals, based on positive screening results, to HCV specialists will be exhibited within the target population at the end of 3 months.

### Literature Review

A literature review was performed to identify strategies necessary to improve primary care provider compliance with USPSTF 2020 HCV universal screening recommendations. The literature revealed barriers to screening for HCV included cost, access, and negative stigma. The stigma of Hepatitis C infection creates a barrier to voluntary screening and needs to be minimized for better screening success (Young et al., 2021). The cost of standard HCV-Ab plus HCV-RNA testing is more expensive than the single reflex test (Asker et al., 2021; Hu & Cui, 2016; Younge et al., 2021). Direct referrals from the provider were more effective for patients seeking treatment post-screening than patient-directed referrals; screening ( $p = .025$ ), follow-up

discussion ( $p = .009$ ), and treatment ( $p = 0.01$ ). Provider-initiated orders for HCV screening have a higher likelihood of treatment start than those initiated through patient concern (OR 9.13,  $p = .005$ ) (Hsiang et al., 2022). Continuous efforts to maintain a process of screening and treatment being managed by the same provider can increase compliance (OR 0.75 [95% CI, .68–.83];  $p < .001$ ). The implementation of screening within the emergency department has been effectively shown to increase the capture of positive HCV infection when using the universal screening methods in comparison to previous USPSTF recommendations (Doyle et al., 2021; Park et al., 2021). Bulk orders, electronic reminders, and mailed reminders with pre-prepared orders for screenings were shown to improve compliance in multiple studies (Hojat et al., 2020; Mehta et al., 2021; Dasai et al., 2021). In a randomized control trial of 12,386 eligible participants, screening for HCV increased when confronted by a provider and combined with an explanation of the risk, benefits, and screening procedure (14.6%, 95% CI [13.8%-15.4%]) (Dasai et al., 2021). Additionally, conversation between the provider and patient was the largest factor contributing to improved screening compliance (Mehta et al., 2021; Dasai et al., 2021; Klein et al., 2021). In each of the four quality improvement studies, a strong theme included the presence of persistent episodic reminders for consistent HCV screening follow-through.

### **Methodology**

This quality improvement (QI) project evaluated the new recommendation for HCV screening during preventative care visits. The design of the project was constructed as a longitudinal design containing a baseline chart review, and intervention implementation through an educational session about HCV screening recommendations in August 2023. The retrospective chart review was performed from May 2023 to July 2023, the three months before the implementation of the educational intervention. A prospective chart review of the three months after implementation, from September 2023 to November 2023, was performed to measure the effectiveness of the intervention.

The sample size calculations for baseline charts review were based on the total population of approximately 258 eligible charts within three months, with a confidence interval level of 95%, a maximum margin of error of 5%, and a 50% response distribution. At least 155 charts were required at baseline and follow-up review (Raosoft Inc., 2021). Chart reviews were performed using ICD and CPT code searches. Randomized convenience sampling was performed on all qualifying Z00.0 and Z00.1 visits. Only charts from participating providers were reviewed. The number of eligible charts exceeded the minimum requirements, including 487 subjects.

### **Intervention**

The key intervention was an educational session on August 24th, 2023, provided by the project leader. The educational session was conducted over a work-day lunch hour with the providers, nurses, and additional staff. The session informed providers of the new HCV screening recommendations and specifics on how to order HCV-Ab, and HCV-RNA PCR reflex testing for preventative care visits. Educational materials included the USPSTF recommendations and rationales, codes for ordering HCV screenings, the cost of screening to varied insured and uninsured patients, and referral information for local HCV treatment specialists. After the education session, infographics were posted in each patient room in view of the provider and patient, to remind the provider to order screening and prompt the patients to ask questions about HCV screening. Furthermore, monthly face-to-face visits with the providers were made by the project leader.

### Tools/Measures

Data was collected on the target population through a report generated by the clinic manager. All data collected was entered into an Excel file on the project manager's password-protected computer. Data were then entered into a Statistical Package for Social Sciences (SPSS) database. Descriptive statistics were used to capture demographic data obtained from the chart review. The chi-squared independence test was used to compare changes before and after the intervention and analysis of nominal-level data. Ratio level data was analyzed using the independent *t*-test. Measures of clinical significance, such as effect size, odds ratio, and 95% confidence interval, were also calculated. Statistical significance was defined as  $p \leq .05$ .

Objective 1 rates of ordered screenings by the provider at preventative health appointments defined as Z00.0 and Z00.1 ICD-coded appointments, were measured as *screened* and *not screened*, based on applied 86803 CPT screening code for HCV-Ab, HCV-RNA-PCR reflex testing versus no screening code when comparing retrospective and prospective chart reviews for the previous and post interventional periods. Positive HCV screening referrals to a hepatitis treatment specialist were recorded on an Excel spreadsheet for both previous and post-intervention periods and used for Objective 2 percentage comparison.

### Evaluation

#### Overall Demographics

A total of 487 subjects met the criteria inclusion requirements and were included in the sample, 199 subjects in T1 and 272 subjects in T2. The predominant age group was 60-69 (24.6%,  $n = 120$ ), followed by 70-79 (24%,  $n = 117$ ), 50-59 (14.2%,  $n = 69$ ), 40-49 (11.9%,  $n = 58$ ), 18-29 (10.1%,  $n = 49$ ), 30-39 (6.8%,  $n = 33$ ), 80-89 (6.6%,  $n = 32$ ), and 90-99 (1.8%,  $n = 9$ ). The sample was female (53%,  $n = 258$ ), with 229 males (47%). The subjects were White (80.1%,  $n = 390$ ), followed by Other Race (19.1%,  $n = 93$ ), and Black or African American (0.8%,  $n = 4$ ). The primary payer was Medicare/Medicaid (43.9%,  $n = 214$ ), followed by BCBS (34.5%,  $n = 168$ ), Other (9.9%,  $n = 48$ ), UHC (5.1%,  $n = 25$ ), Aetna (3.3%,  $n = 16$ ), Self-Pay (2.5%,  $n = 12$ ), Tricare (0.6%,  $n = 3$ ), and Humana (0.2%,  $n = 1$ ). There was no statistically significant difference between the groups for age ( $p = .178$ ), gender ( $p = .398$ ), or race ( $p = .282$ ) between T1 and T2. Insurance type was statistically significant between the groups ( $p = .009$ ); T1 had 67 individuals with MCR/MCD and T2 had 147 individuals with MCR/MCD.

**Subjects consented to screen.** Of the 199 subjects in T1, zero consented to screen; of the 272 subjects in T2, 16 subjects (5.6%) consented to the screening. Subjects in T2 saw a small to moderate statistically significant increase in consent to screening than T1,  $\chi^2(1) = 11.431$ ,  $p < .001$ ,  $\phi = 0.2$ . When asked about HCV screening, patients were two times more likely to consent to screening post-intervention (OR = 1.732, 95% CI [1.603, 1.871].) Of the 16 subjects who consented to screen there were eight males and eight females. Three of the 16 subjects identified as Other Race and 13 identified as White. The majority of those that consented to screen were 60-69 years ( $n = 5$ ), 50-59 years ( $n = 4$ ), 70-79 years ( $n = 3$ ), 18-29 years ( $n = 2$ ), and one 30-39 years and one 40-49 years. Of those who consented to screen there were seven with BCBS, seven with MCR/MCD, and two with UHC.

**Subjects successfully screened.** Because zero subjects consented to screening, zero followed through with HCV screening from T1 (0%,  $n = 199$ ); of the 16 subjects that consented to screening from T2 ( $n = 272$ ), 10 subjects (3.5%) completed screening. Subjects in T2 saw a small to moderate statistically significant increase in completed screening than T1,  $\chi^2(1) = 7.055$ ,  $p = .008$ ,  $\phi = 0.2$ . Of the 10 subjects who completed the screening, there were seven females and three males. Three of the 10 individuals identified as Other Race and seven

identified as White. Those who completed the screening were 60-69 years ( $n = 5$ ), 70-79 years ( $n = 3$ ), 50-59 years ( $n = 1$ ), and 40-49 years ( $n = 1$ ). Of those who consented to screen there were five with MCR/MCD, four with BCBS, and one with UHC. The predominant insurance in the T2 group was MCR/MCD ( $n = 5$ ), followed by BCBS ( $n = 4$ ) and UHC ( $n = 1$ ).

**Provider referral to specialist compliance.** Zero individuals from T1 were identified as requiring HCV treatment, due to the lack of screening. In T2, one screened individual (0.3%) was found to be positive using the reflex PRC/Antibody HCV screening and confirmatory test. This one individual from T2 was referred to a specialist for HCV treatment, which was not statistically significant,  $p = .41$ ,  $\phi = .04$ . The one individual referred for treatment was within the 40-49 years category, identified as White, male, and insured under MCR/MCD

### **Conclusion**

This project evaluated the HCV educational intervention in association with HCV screenings and referrals for treatment following the USPSTF 2020 guidelines. An increase from zero screenings to 10 screenings and one patient referral was completed after the interventions were implemented. However, a percentage change cannot be quantified between the two differing timelines, given T1 had no consents, screenings, or referrals performed. The intervention did yield a small to moderate increase in screenings for HCV at primary care visits. An increase in referrals was clinically observed but without statistical significance.

### **Recommendations**

The biggest variable not accounted for statistically and likely to impact the decision to screen was the cost of the screening to the subject. While some insurance companies did pay for the screening, such as Medicare and BCBS, others did not, and the patient was left to pay approximately \$450 out of pocket. Insured patients were therefore at the advantage of completing the screening which was reflected in the demographic analysis. White individuals were also at a higher percentage of completing the screening which suggests further analysis into social determinants of health that may impact these decisions and influence the providers' language around the proposition of screening. A qualitative analysis would be beneficial to understand further the barriers and limitations providers face when conversing with patients about the option to screen.

### **Strengths and Limitations**

The strengths of this project include the demonstration of small to moderate statistical significance and objective clinical significance for those who tested positive for HCV and found treatment options before serious harm became evident. Limitations of the project included the use of convenience sampling. If this project were to be replicated in the future, it is advised to implement a more streamlined approach to record-keeping and analytical documentation rather than an itemized chart review. Overall, HCV screening can be implemented into a primary care examination with only the interventional factors implemented in this study to support the providers. However, insurance denial and self-pay costs must be considered as major barriers to increasing screening rates.

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Appendix A

DNP D1 Form



DNP Residential Project Committee Appointment Request

Student's Name: Lauren Hightower
Student's Number: 18161025
Date Submitted:

I request that the faculty members listed below be appointed to serve as my Residential Project committee.

Dr. Gina Oliver

Name of Chair\*
Dr. Jan Sherman

Gina Oliver PHD, APRN, FNP-BC, CNE
Signature, Chair of Committee

Member\*

Dr. Jan Sherman
Signature, Member

Concetta Martin, PA-C
Member\*

Concetta W. Martin, PA-C
Signature, Member

Member\*

Signature, Member

Lauren Hightower, BSN

Miriam D. Butler, DNP, NP-C, FNP-BC
Signature of Director of DNP Program, School of Nursing

Signature of Student
\*Please type or print

To be completed during the semester enrolled in:
N9080 Section 1 DNP Residency Project

Appendix B

DNP D-3 Form

**M** **Approval of DNP Residency Project Proposal and the Institutional Review Board Protocol**

Candidate's name: Hightower, Lauren Mizzou ID number: 18161025  
(Last Name, First Name)

Project Title: Hepatitis C Viral Screening in the Primary Care Setting

**Signatures of review members**  
 (Please sign full names legibly)

	Acceptable	Unacceptable
Chair: <u>Gina Oliver PhD, APRN, FNP-BC, CNE</u> <i>Gina Oliver PhD, APRN, FNP-BC, CNE</i> <small>print &amp; sign</small>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Member: <u>Jan Sherman PhD, RN, NNP-BC</u> <i>Jan Sherman, RN, NNP, PhD</i> <small>print &amp; sign</small>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Member: <u>Concetta Martin PA-C</u> <i>Concetta Martin, PA-C</i> <small>print &amp; sign</small>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Member: <u>N/a</u> <small>print &amp; sign</small>	<input type="checkbox"/>	<input type="checkbox"/>

The clinical project is:

The Program Committee has explained the decision regarding the acceptability of my project proposal.

*Lauren Hightower* 7-23-23  
 Student Signature Date

**Miriam D. Butler, DNP, NP-C, FNP-BC** Digitally signed by Miriam D. Butler, DNP, NP-C, FNP-BC  
 Date: 2023.07.24 08:55:29 -05'00'

Director, DNP Program in Nursing Date