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Impact of Pharmacist Involvement in Hepatitis C Screening in a Rural Native American Population

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ABSTRACT:

Introduction: Many patients in the 6,000 square mile service area of the Navajo and Hopi reservations have difficulty obtaining care from facilities outside of Tuba City Regional Health Care Corporation (TCRHCC) due to difficulty with transportation, the remoteness of the location, and limited access to health care. At the beginning of this study, patients diagnosed with Hepatitis C Virus (HCV) would be referred over 200 miles south of TCRHCC.

Objectives: The primary goal of this research was to assess the need for a pharmacy-managed HCV clinic at TCRHCC.

Methods: Retrospective data was collected on all patients at Tuba City Regional Health Care Corporation who had a positive test result or diagnosis for HCV between 1/1/2010 and 9/1/2022 in order to assess historical need. An education session was led for providers to review the recommendations for screening, diagnosis, and treatment of HCV, along with sharing the collected data. The health screening tool used by TCRHCC was also updated to reflect current guideline recommendations.

Results: Data collected from 1/1/10 and 9/1/22 showed that there were 147 patients who tested positive or were diagnosed with HCV, and none of them had a record of being cured despite 2 being treated at TCRHCC and 21 being referred out. After the provider education and update to the health screening tool, the rates of HCV antibody and RNA tests increased in 2023 compared to the same month in 2022. There was no change in the number of patients being treated at TCRHCC for HCV by the infectious disease physician due to insufficient time.

Conclusion: Based on the data collected in this study, guideline recommendations, and the increase in patients needing to see an infectious disease physician for care, TCRHCC would likely benefit from a pharmacist-managed HCV clinic.

Introduction

Tuba City Regional Health Care Corporation (TCRHCC) is an accredited health center that provides services to a 6,000-square-mile area of the Navajo and Hopi Reservations in northern Arizona. Medical providers at TCRHCC have reported concern relating to a lack of treatment and follow-up offered for patients who test positive for Hepatitis C Virus (HCV). Currently, most patients diagnosed with HCV are referred to Phoenix for care, which is nearly a 3.5-hour drive south. This distance poses an issue for the population due to the time commitment and difficulty obtaining reliable transportation.

Hepatitis C Virus (HCV) is a contagious viral infection that causes liver inflammation and often leads to chronic liver infection. American Indians and Alaska Natives have the highest rates of HCV as of 2015, and from 2011 to 2015, mortality has increased by 13%.[1] In 2020, the Centers for Disease Control and Prevention reported that acute cases of HCV were highest amongst American Indian and Alaskan Native people at 66.8 cases per 100,000 people.[1] Additionally, the death rates were 3.2 times higher when compared to non-Hispanic white persons.[1] A study of 11 separate Indian Health Service sites in Kansas and Oklahoma demonstrated that pharmacist involvement in HCV care expands access and improves patient outcomes.[2]

TCRHCC needs to develop a standardized method for the identification and treatment of patients with HCV that better suits the needs of its patient population. This study was designed to determine if pharmacist involvement in the identification and treatment of Hepatitis C infection would lead to an increase in HCV screening, increased patient access to care, and expanded pharmacy services.

Objectives

The primary goal of this research was to assess the need for a pharmacy-managed hepatitis C virus clinic at TCRHCC. The following objectives were made to help achieve this goal:

1) Increase provider awareness of best practices for screening and diagnosing HCV.
2) Establish a standardized protocol for the screening of HCV.
3) Evaluate patients properly to assess candidacy for treatment.
4) Enhance the role of pharmacy in providing care for HCV patients.
5) Increase patient access to care.
6) Decrease the prevalence of HCV in the community.

Methods

Retrospective data was collected on all patients at Tuba City Regional Health Care Corporation who had a positive test result or diagnosis for HCV between 1/1/2010 and 9/1/2022. Data collected included patient sex, patient age, the clinic where the test was conducted, ordering provider, date of positive tests, type of positive test, whether a referral was placed, if the patient received treatment from TCRHCC, if tested for a cure, and HIV status. The sex assignments used in this study are the ones patients were assigned at birth. This data was then presented to the providers at TCRHCC, along with education on the recommendations for screening, diagnosing, and treating people with HCV risk factors or HCV, according to the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America.[3] Prior to and immediately after this educational session was led, a survey was sent to the providers to assess their level of knowledge and comfort with screening and treating HCV. The most recent guidelines state that "one-time, routine, opt-out HCV testing is recommended for all individuals aged 18 years or older."[3] to assess patients for HCV. For those who test positive to the HCV antibody screening test, an HCV RNA test should be ordered for confirmatory testing of an active HCV infection. If the HCV RNA test is positive, the patient may be referred to the infectious disease provider for treatment.

In addition to educating providers, two other methods were used to increase the appropriate screening, diagnosis, and treatment of HCV at TCRHCC. The electronic health record at Tuba City Regional Health Care Corporation has a general health screening tool that has pop-up alerts for patients based on vaccines, regularly scheduled labs, and other common guideline recommendations based on the age, sex, and diagnoses of the patient. Hepatitis C virus screening was added to this system for all patients who meet the eligibility criteria. Additionally, a medication was added to the TCRHCC formulary that is used in the treatment of HCV. This is the first medication used for the treatment of HCV to be added to our formulary. Data on HCV screening and diagnoses was collected before and after these initiatives were instituted and compared one year apart.

This study did not conduct research on human participants and, therefore, did not need IRB approval.

Results

Data on the clinic where HCV testing occurred from 1/1/2010 through 9/1/2022 was collected and is shown in Table 1. Over that period of nearly 12 years, 147 patients were diagnosed with or tested positive for HCV at TCRHCC. The cascade of care for the patients who tested positive for HCV is shown in Figure 1. In order to be included in the "Total Patients," patients had a positive HCV antibody test, RNA test, or diagnosis code of hepatitis C virus. Of the 147 patients, 62 had a positive HCV RNA test confirming diagnosis. There were 21 patients referred to an outside facility for treatment, and two patients were treated at TCRHCC. None of the patients with a positive HCV test have a record of being cured. Three patients had a coinfection of HIV. This data is available upon request.

Data that was intended to be collected and evaluated include the following:

1) Change in provider comfort in the knowledge of HCV before and after an educational presentation
2) Number of patients screened, diagnosed, treated, and cured of HCV after the systemic changes had been instituted and the education was given to the providers
3) Number of patients with follow-up testing for sustained virologic response 12 weeks after the completion of HCV therapy
4) Identification of potential risk factors for infection and reinfection based on the cases of patients with positive HCV RNA tests.

The majority of this data is waiting to be collected, presenting a valuable opportunity for progress.

There were multiple causes for the data collection not being as complete as anticipated.

1) The data was collected appropriately and with a high response rate prior to the education, but data was collected from only one provider after the education. This was due to a clerical error resulting in the post-survey not being listed as a requirement for completion of the education.

2) There were delays in making the proposed changes which limited the amount of data to be evaluated. Comparative data was collected on differences in screening and diagnosis between 2022 and 2023.

3) Very few patients have been treated due to the limited available time of the infectious disease physician at Tuba City Regional Health Care Corporation. Of those who began treatment, none have yet been tested for cure of HCV.

4) There is no data due to few cases being investigated and treated since the changes have been made at TCRHCC.

Screening and diagnostic testing has increased from January through June of 2023 compared to 2022. There were 888 HCV antibody tests completed in 2022 and 1415 in 2023. For HCV RNA tests, there were 9 in 2022 and 11 in 2023.

Discussion

Based on the cascade of care shown in *Figure 1*, TCRHCC does not have a positive historical record for the treatment of HCV. This data was used as justification for the need for efforts to be made to improve care related to HCV. Based on the gaps in care shown with this data, the initiatives stated in the methods were created to close these. The increase in HCV antibody and RNA tests demonstrates that these efforts were successful at improving screening and diagnostic testing. After the proposed improvements had been made, the rate-limiting step in the patient care process became the actual treatment of patients. The limited time of one infectious disease physician for the healthcare corporation has manifested in a delay in patient care for those with HCV who need treatment.

Some strengths of this study include the multimodal approach to improve patient care relating to HCV, providing qualitative (provider education) and quantitative (health screening tool) measures for improvement, and sustainability of changes.

Limitations of this study include an incomplete collection of the anticipated data, limited generalizability of the results of this study to healthcare systems in more populous regions, and the potential bias due to a lack of blinding and randomization.

The results of this study show a correlation between the increase in pharmacy involvement in HCV care and the increase in HCV screening. These results were anticipated from the onset of the study, although additional data was expected in regard to changes in provider comfort with HCV and HCV treatment and cure rates. Increasing HCV testing for TCRHCC patients increases overall healthcare system costs directly and through follow-up costs, which are associated with positive results. The cost to treat one patient for HCV is over $11,000 for just the treatment medication, but pre-treatment labs and provider time are additional factors that increase costs. These costs result in a decreased risk of chronic HCV infection, cirrhosis, hepatocellular carcinoma, hepatic decompensation, and the need for a liver transplant, in addition to an improved quality of life for the patients.

Conclusion

Given the currently available data, guideline recommendations from the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, and the increase in patients needing to see an infectious disease physician for care, TCRHCC would likely benefit from a pharmacist-managed HCV clinic. With an appropriate foundation, this can be a sustainable change to improve the care of patients at TCRHCC with HCV.

Key Points

What was already known

1) Hepatitis C Virus (HCV) is a contagious viral infection that causes liver inflammation and leads to chronic liver infection

2) In 2020, the Centers for Disease Control and Prevention reported that acute cases of HCV were highest amongst American Indian and Alaskan Native people

3) Patients at Tuba City Regional Health Care Corporation have difficulty getting treatment for HCV due to the rural location and limited resources

What this study adds

1) Ways to improve screening and diagnosing based on guideline recommendations

2) Consequences of provider education and systemic changes on practice results

3) A pathway to provide treatment to HCV in a rural, underserved population

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Appendix

Figure 1

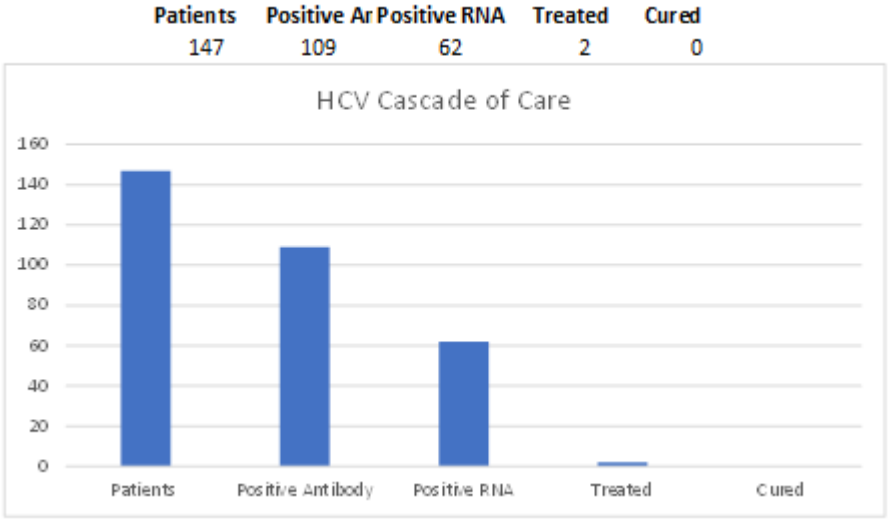

Table 1: Most HCV Diagnosis in TCRHCC per Clinic

Clinic	HCV Diagnoses (n = 147)
Sacred Peaks	15% (22/147)
Same Day	14% (20/147)
Emergency Department	12% (17/147)
Family Medicine	10% (15/147)
Internal Medicine	7% (10/147)
Women's	5% (8/147)