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“ : Hepatitis C Screening, Confirmation, and Referral Improvement Project ”

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**Will Adding a Hepatitis C Screening Reminder in the EMR Along with Provider Education
Improve Screening, Confirmatory Testing, and Referral to the Treatment Care Cascade?**

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Abstract

Hepatitis C is an illness caused by the bloodborne Hepatitis C virus (HCV), and usually becomes a chronic condition. Left untreated it can lead to severe liver disease and liver failure. Newer treatments are effective and well tolerated, but most people with chronic HCV are not accessing treatment due to several factors that will be discussed. The primary objectives of this quality improvement (QI) project are to improve the treatment cascade, provide education to providers and patients, and facilitate screening, virus confirmation, and referral to treatment, in a Federally Qualified Health Center (FQHC).

Keywords: Hepatitis C, screening, linkage to care, primary care.

Dedication

I dedicate this scholarly project to my family, particularly my husband and children, who have encouraged me and supported me throughout the past 2 years. I dedicate my efforts to my patients, many of whom are disadvantaged and vulnerable. My hope is that my efforts will help to decrease disparities, and improve access to treatment for all patients who desire it.

Acknowledgments

I would like to thank my project chair, Dr. Joanne Haeffele, and my committee member, Dr. Aaron Skiles, for their feedback, support, and encouragement throughout this project. Thanks also to Blake Boursaw for his statistical expertise. I would like to thank UNM and Project ECHO for their diligent work in Hepatitis C education, training, and involvement in policy change. Thank you also to La Familia Medical Center for supporting me in this project, especially to Lorie Martinez MA, and Irene Berenstein CHW, both of whom work tirelessly in the Hepatitis C treatment program.

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**Will Adding a Hepatitis C Screening Reminder in the EMR Along With Provider
Education Improve Screening, Confirmatory Testing, and Referral to the Treatment Care
Cascade?**

Chapter 1 – Introduction

Background

Hepatitis C virus is the most common blood borne disease in New Mexico. As of 2018, 53,000 New Mexicans (about 2.5% of the population) had been exposed to HCV, most of whom developed chronic infection (NM-IBIS, 2018). Treatment is available, but patients need to be screened and treated in order to have an impact on this contagious and potentially deadly infection.

Hepatitis C is an infection in the liver caused by the hepatitis C virus. Acute infections range from mild to severe, and most often lead to a chronic infection. Chronic infections can lead to liver fibrosis, cirrhosis, liver cancer, and liver failure. The U.S. Centers for Disease Control and Prevention (CDC) has developed a strategy to eliminate HCV in the U.S. outlined in The National Academy of Science, Engineering, and Medical Reports (NASEM) on Viral Hepatitis (CDC, 2020). As of 2020, the current estimate of the number of individuals with chronic HCV in the U.S. is 3.2 million (Healthy People 2020, n.d.). Healthy People 2030 has set goals of decreasing deaths from HCV from 3.33/100,000 (rate from 2019) to 1.44/100,000. They have also set a goal of decreasing the rate of HCV from 1/100,000 seen in 2017, to a target of 0.1/100,000. Lastly, they have set a goal of improving the percent of individuals cured of chronic HCV infection from the 42.5% seen from 2013-16 up to a goal of 80% (ODPHP, n.d.).

Historically, the focus of screening was the Baby Boomer generation born between 1945-1965, but from 2010 to 2017, the incidence of HCV infection almost quadrupled. This was

primarily due to injection drug use related to the opioid epidemic, and the rise in cases was seen largely in the 20–39 years age group (CDC, 2017). In light of this, the U.S. Preventive Services Taskforce (USPTF) (2020) has recommended universal one-time screening for all adults up to age 79. This cost-effective strategy has proven robust in a variety of settings including correctional, prenatal, primary care, and substance use treatment centers (Ghany & Morgan, 2020).

The advent of newer direct-acting antiviral medications has improved the treatment landscape significantly. These newer medications are safe, well tolerated, and highly effective, and have a greater than 95% cure rate (Falade-Nwulia et al., 2017). Elimination of HCV as a public health threat is now conceivable. Key elements of the elimination plan include improved identification of undiagnosed individuals, increased linkage and access to care for newly diagnosed individuals, and expanded treatment access. Simplified treatment algorithms for those who are treatment naïve and non-cirrhotic should ease treatment burden (CDC, 2020). The most basic of treatment cascades includes: 1) documentation of HCV antibody, 2) patient notification of result and availability of care, 3) viral load confirmation, 4) referral to treating provider and staging of liver disease, 5) treatment medication received and taken, and 6) sustained virologic response (cure) (Hachey et al., 2019).

New Mexico (NM) has been at the forefront of HCV treatment for many years. The stated goal of the NM Hepatitis C Coalition is to prioritize the prevention, testing, and treatment of HCV infection, in order to decrease the number of new infections, cure active infections, and reduce the negative impact of the disease (Snow et al., 2016). As of 2018, NM had at least 53,000 individuals with HCV (2.5% of the population) (NM-IBIS, 2018). This number is about the same as previous estimates from prior years. Though the treatment has become easier and

more accessible, there are more patients contracting HCV, and linkage to treatment is less than 10% (Ghany & Morgan, 2020). Dr. Sanjeev Arora, from the University of New Mexico, developed a program to extend HCV care into all of NM called Project ECHO (Extended Community Healthcare Outcomes). Dr. Arora and his team have provided guidance to over 165 providers in NM and the U.S. that has allowed care to countless patients (Project ECHO, n.d.). As proactive as NM has been, the number of untreated individuals with active infection is still high. In order to decrease these numbers meaningfully, successful treatment regimens should be provided to individuals with known infections, and undiagnosed cases should be identified and referred to care.

Problem Statement

La Familia Medical Center (LFMC) is a Federally Qualified Health Center (FQHC) in Santa Fe, NM. LFMC sees over 18,000 individual patients annually, over 14,000 of whom are adults, and over 10,000 of whom live at or below the poverty level. Since 2018, 4529 individuals 18 years old and older have been screened for HCV (31% of the adult patient population), 320 (7%) of whom had a positive antibody test. Of those, 223 (70%) have had confirmatory testing, with 142 having an active viral load (64% positivity rate). LFMC has identified a total of 315 patients as having active, untreated Hepatitis C (diagnosed but not treated), and has not yet screened 69% of its current adult patient population. LFMC has an active Hepatitis C treatment team consisting of one provider, one medical assistant, and one HCV Program Coordinator/Navigator. All of the primary care providers (PCP) at the clinic are aware of the availability of treatment on-site. Providers have been encouraged to universally screen patients for HCV antibody but there had not been an electronic reminder. Reminders in the electronic medical record (EMR) have been shown to increase the screening rate for HCV (Gemelas et al., 2016;

Yakovchenko et al., 2019). If a patient is HCV antibody positive, a confirmatory test should be ordered by the PCP, but this is not always done. The HCV navigator tracks these, and guides patients through further testing once a referral is received from the PCP. If chronic HCV is diagnosed, the navigator will refer to the HCV treating provider. Though this is not a formal treatment cascade, it does informally address some of the steps of the cascade. Overall, about 203 patients have entered and completed treatment over the past 4 years.

This quality improvement project has been designed to increase patient screening and formalize an HCV treatment cascade. Educating providers and implementing an EMR reminder, providing HCV information to patients at the time of screening, and expediting confirmatory testing should all help to optimize the process of identifying patients with chronic HCV. This should lead to an increase in the number of patients referred to treatment.

PICOT Question

For adult patients at LFMC, will adding an HCV screening reminder in the EMR along with provider education improve screening, confirmatory RNA testing, and referral rates to benefit the HCV treatment care cascade for LFMC adult patients over 90 days in 2021, as compared to 2020?

Objectives and Aims

The main objectives in this project are to get more patients screened for HCV, and to link those with chronic HCV into the treatment cascade. To meet these objectives, I propose to provide education to providers and patients, increase screening rate and confirmatory testing, and have a referral process in place by:

1. Having a reminder placed in the current EMR. If a patient has previously been tested, the requirement is fulfilled, but if not, it will display an alert that will prompt the provider to order screening.
2. Educating providers on current HCV screening recommendations, and assuring they are aware of the EMR reminder.
3. Stressing the importance of a conversation about HCV screening with eligible patients.
4. Providing HCV education to every person being screened, available in English and Spanish (CDC handout).
5. Assuring positive antibody tests have confirmatory RNA testing done to assess for chronic infection.
6. Advising patients and their providers of HCV status and referring for treatment when indicated.

Chapter 2 - Literature Review

Population Screening

HCV screening is ideally done through a person's primary care provider (PCP), but has been successful in a variety of settings (Ghany & Morgan, 2020). Using a public health approach to identify and refer patients with chronic HCV has been successful in some larger cities, through Community Health Centers, FQHCs, and syringe exchange programs. The public health model was found to be effective in identifying, diagnosing, and linking individuals with chronic HCV to care (Ford et al., 2018). Expanding the public health role to educate about risks and treatments, reduce barriers, and provide support increased the number of individuals treated and cured (Laraque et al., 2017). Frequently hospitals test for chronic HCV, but Sherbuk et al. (2018) found that diagnosis during inpatient or ER visits had a much lower linkage to care rate than those that were diagnosed in the outpatient setting.

Models to Improve Screening

HCV is the most common blood borne viral infection, but oftentimes screening is not done. With the newer recommendation of universal HCV screening of all adults, getting more patients screened presents a challenge. Integrating routine HCV testing into primary care as an opt-out program has shown promise in increasing screening, confirmation of HCV, and linkage to care (Coyle et al., 2016).

Many systems have implemented an EMR prompt for HCV screening. Several studies have demonstrated a significant increase in HCV screening over the first year of implementation (Konerman et al, 2017; Gemelas et al., 2016; Miller et al., 2016). Qualitative studies done after the implementation of an EMR prompt showed the prompt to be the best cue for testing, and most providers felt it was a helpful reminder and was not burdensome (Yakovchenko et al.,

2019; Gemelas et al., 2016). A quality improvement project using the Plan-Do-Act Model improved the outcome measures of HCV antibody screening, viral load confirmation, and linkage to care (Bakhai et al., 2019).

Barriers and Facilitators to Screening

HCV screening is typically ordered by the PCP. There are many reasons why providers do or don't order screening. Often, providers are reluctant to offer screening or treatment if the patient is still using alcohol or illicit substances, or has a history of mental illness (Yakovchenko et al., 2019). But, Kim et al. (2018) found that having a substance use disorder or mental illness did not affect a person's ability to link to care. Providers were more prone to counsel patients on HCV and to recommend screening and treatment if there was a known high disease burden in the clinic setting (Gemelas et al., 2015, Miller, et al., 2016). Providers were also more prone to offer screening and treatment if they were aware of the newer curative treatments, and if there were support services in place, especially "treatment champions" (Yakovchenko et al., 2019).

The presence of treatment champions, care coordinators, project coordinators, nurse navigators, and multidisciplinary teams had a strong association with increased screening and linkage to care (Miller et al., 2016; Turner et al., 2019; Bakhai et al., 2019). Higashi et al (2020) found that lack of knowledge and stigma play major roles in suboptimal screening.

Barriers and Facilitators to Linkage to Care

In 2016, the national rate for individuals with chronic HCV to be linked to care was 17% (Reau et al., 2018). Barriers to linkage to care were patient and provider lack of knowledge (Hachey et al., 2019) and race, with Blacks having the highest rate of HCV antibody positivity and the lowest rate of linkage to care (Kim et al., 2018). Linkage to care was improved using a nurse navigator model and enhanced patient tracking (Sherbuk et al., 2019; Coyle et al., 2016).

Improved linkage to care has been demonstrated by using telemedicine, advanced practice providers, established substance abuse services, and primary care clinics (Zuckerman et al., 2018).

Special Concerns: Individuals Who Use Substances

The American Association for the Study of Liver Disease (AASLD) recommends at least annual screening for individuals who are at increased risk of HCV exposure, such as those who are currently injecting drugs, using illicit intranasal drugs, getting tattoos in an unregulated setting, being incarcerated, and men who have unprotected sex with men (Ghany & Morgan, 2020). The National Institutes of Health (NIH) report that individuals who are actively injecting illicit drugs are most severely affected by chronic HCV, but they are the least likely to receive treatment. Several studies have shown successful HCV treatment in individuals actively injecting drugs, when sufficient support services were in place (Edlin et al., 2007), and treatment of this group is recommended by AASLD (2019).

The main barriers to treatment for persons who inject drugs (PWID) were lack of knowledge, fear of treatment, cost of treatment, and insurance coverage. Facilitators to treatment were availability of transportation, HCV treatment available at the same site, report from a friend that HCV treatment had helped them, and having a friend or a partner who was concerned about their chronic HCV infection (Falade-Nwulia et al., 2019). Individuals who misused substances were more likely to link to care and complete treatment when linked to a clinic with embedded support services (Sherbuk et al., 2018). Engaging PWID with mental health services and social services increased uptake in HCV linkage to care and treatment (Zuckerman et al., 2018).

One of the most promising programs to engage PWID with treatment was the Medication-Assisted Treatment (MAT) program, which uses buprenorphine to treat opioid

dependence. For PWID, retention in MAT was associated with improved linkage to care, and retention in treatment programs. The programs often provide patients with an opportunity to access HCV treatment, which reduces transmission, morbidity, and mortality once the HCV is treated (Norton et al., 2017).

Co-Located Clinic Sites

The last factor that had an effect on successfully linking patients to care was the location of the treatment clinic. The availability of a co-located HCV treatment clinic likely contributed to high linkage to care rates because patients were familiar with the clinic location, staff, and operations. The presence of a treatment clinic on site also improved PCP familiarity with treatment and improved the HCV exam in the primary care setting (Miller et al., 2016). Falade-Nwulia et al. (2019) also noted in their qualitative study that treatment availability at the same site was a facilitator to linkage to treatment. Coyle et al. (2019) performed a retrospective study among five FQHCs, one of which was a “test and treat” site. They found that individuals with chronic HCV were successfully linked to an HCV provider more often in the “test and treat” site compared on average over the other clinical site types (81% vs 58%). They also stressed the importance of adding HCV treatment services to HCV testing sites in order to improve access to treatment.

Chapter 3 – Methodology

Theoretical Model

The Model for Improvement (Appendix A) was developed by the Associates in Process Improvement. It asks three fundamental questions about the desired change, which are considered the “Aim” of the project, then incorporates the Plan Do Study Act (PDSA) cycle that was developed by Edward Demings in 1950. The three questions are:

- 1) What are we trying to accomplish?
- 2) How will we know that a change is an improvement?
- 3) What change can we make that will result in improvement?

The PDSA cycle is illustrative for testing a change by “planning” it (P), “doing” it (D), observing or “studying” the results (S), and “acting” on what is learned (A). By testing the change on a smaller scale, one can easily assess if the change is beneficial, needs modification, can be taken to a larger scale, or should be discarded (IHI, 2021). Bakhai et al. (2019) successfully used the PDSA with nine cycles over a 24-month period to increase the screening rate of HCV in their facility by 27%.

The Model for Improvement has been used by hundreds of health care organizations to improve many different health care processes and goals. The aim of the project should be time-specific and measurable, and should define the affected population. Quantitative outcome and process measures are plotted on a chart to see effects of the change quickly and easily over time (IHI, 2021). The Model for Improvement is an ideal model for assessing effectiveness of QI projects, as it includes visualization of change effects, and allows for modification of processes as needed if the initial change is not effective.

Project and Study Design

The aim of this project was to increase the number of eligible adult patients screened for HCV, have confirmatory testing done if antibody positive, and have a referral for treatment in place if chronic HCV was present. A change was an improvement if there was an increase in screening by 10% over a three-month period, and if there was an increase in confirmatory testing and referral for treatment when indicated. The placement of an EMR screening reminder, provider education, and patient handouts should have lead to the desired improvement. The PDSA cycle was used to monitor the effects of the change and to guide further improvement.

Setting and Resources.

This quality improvement project took place within La Familia Medical Center. LFMC is an FQHC in Santa Fe, NM that serves over 18,000 individual patients annually, more than 10,000 of whom live at or below the poverty level. It is comprised of three sites: the main “Alto” clinic, the “Southside” clinic, and the Healthcare for the Homeless clinic. LFMC is staffed by MDs, FNPs, Pharmacists, Behavioral Health (BH) Therapists, Psychiatrists, Medical Assistants (MAs), Case Managers, Community Health Workers (CHW), Lab Technicians, and Patient Service Representatives. Services provided are primary care, specialty clinics, pharmacy, BH support, MAT, and chronic HCV treatment. The group involved in implementing this QI project included Maria McMahon FNP (lead), Lorie Martinez MA, Irene Berenstein CHW, and Ashley Young IT support. For this QI project, I obtained data from all providers for a three-month period in 2020 and again for a three-month period in 2021, after an educational intervention was provided.

LFMC has a process in place to refer patients with chronic HCV to the CHW, who provides HCV education, orders additional appropriate lab tests, and further refers patients to the HCV provider (McMahon). Currently LFMC has screened about 31% of its adult population.

There is a significant subset of patients who have had positive antibody testing but have not had confirmatory testing, and another group of patients who have had positive confirmatory testing but have not been referred for treatment consultation. For purposes of this project, I will not be focusing on these subsets, but on screening patients who have not yet been screened. LFMC has a dedicated staff to care for patients with chronic HCV.

Providers were given updated HCV training during a regularly scheduled monthly provider meeting (discussed under *Implementation*). Patients were given an educational handout when they were screened for HCV.

QI Project Population.

This QI project centered on adult patients (age 18 and over) within LFMC clinic who had not yet been screened for HCV, and those individuals who were new patients establishing their care at LFMC. Exclusion criteria were patient declination of the screening or treatment after being counseled, previous negative screening in a low-risk patient not in need of rescreening, and previous treatment of HCV. Pregnant women were not targeted, nor was pregnancy screened for, for purposes of this project.

Sources of Data

Quantitative data was obtained from the LFMC EMR for a three-month period from July 1 – September 30, 2020, and for the same period again in 2021. Baseline patient data included three months prior to the implementation of the EMR reminder (July – September 2020), looking at the number of screenings done per number of eligible patients seen. Provider post-education data included a three-month period obtained after IRB approval and full implementation of other processes (provider education, patient handouts).

Ethical Considerations and Consent

This QI project was submitted for initial application and had not previously been reviewed by an Institutional Review Board (IRB); it was approved on June 14, 2021. There was no specimen banking associated with this project. All data extracted was for patients age 18 and older, and was de-identified. No drugs or devices were used for this project, and lab-work obtained was standard of care.

The current USPTF (2020) screening guidelines have recently been expanded to include HCV screening of all adults aged 18 to 79 who have not yet been screened. The standard of care is to educate and recommend screening of all eligible adults. Patients consented to care when they arrived in the clinic setting, so additional patient consent was not required. This QI project served to bring the LFMC clinics up to the current standard of care.

Providers attended an educational session on HCV that was presented during a regularly scheduled provider meeting. Using a PowerPoint presentation to educate providers can raise awareness of the disease and increase screening rates (Bakhai et al., 2019).

Ethically, screening should be offered to every eligible person regardless of insurance status, documentation status, language barriers, economic or educational disadvantage, mental or physical disability, and those with current substance use. Learning of a positive HCV status may cause increased anxiety for patients; this is often quelled by discussion of effective treatment options. If patients continued to have anxiety and stress, they would be referred to BH, which was readily available within LFMC.

As an FQHC, LFMC serves Santa Fe and the surrounding communities. Many patients are considered to be part of a vulnerable population, with over 12,000 patients identifying as Hispanic/Latino, and over 7,500 being non-English speakers. Through Spanish-speaking providers or translation services, all non-English speakers should have been fully informed about

screening recommendations and given the opportunity to consent to or decline screening.

Another vulnerable population within LFMC were those who used illicit drugs or had a history of injection drug use. Many of them were identified through the MAT program, and this has been an additional opportunity for screening. By educating patients and being as inclusive as possible, LFMC has acknowledged the ethical principles of autonomy, beneficence, non-maleficence, and justice. Once a patient has been diagnosed with chronic HCV and referred to care, there are programs available to support treatment through the Department of Health, without cost to eligible patients (those not otherwise eligible for Medicaid, Medicare, or commercial insurance).

Consent

A waiver of consent was requested from IRB. This project involved no more than minimal risk to subjects. All data extracted was de-identified and there is no way to associate any information to any patient or provider.

Patient chart data was obtained from all providers within LFMC for the designated time periods. All providers in attendance at the regularly scheduled provider meeting received the educational program as part of LFMC's patient care improvement requirements.

Planning and Procedures

Planning

LFMC has an HCV treatment program in place and has screened about 31% of its eligible adult population for HCV. Many of the current PCPs may not be aware of the current screening guidelines, the effectiveness of the newer medications, or ease of the new treatment protocols. This QI program was planned to increase the number of eligible patients being screened for HCV, confirmed if antibody positive, and referred for treatment when appropriate. The plan included addition of an EMR reminder for screening, and education of the providers

with a PowerPoint presentation. The lab staff were to give any patient being screened an informational handout on HCV results in their preferred language (only available in English and Spanish). In turn, the providers should have educated their patients about the importance of HCV screening, ordered the screening and confirmatory test if indicated, and referred them to treatment if chronic HCV was present. LFMC management has been fully supportive of this project and had suggested the team as outlined previously.

The aim of this project was to increase the number of patients being screened for HCV by 10% over a three-month period. A change in number of patients being screened for HCV was assessed by comparing data pre- and post-implementation of changes.

Implementation

The reminder for HCV screening was recently placed on the EMR system, but LFMC staff had not yet been educated on it. LFMC uses “eClinicalWorks” as their EMR. It provides a tab for “Clinical Decision Support System”, or CDSS. The CDSS is an application that analyzes data to support healthcare providers in making decisions to improve patient care (CDC, n.d.). LFMC has incorporated HCV screening as a quality measure. The EMR screening reminder has been shown to be the best cue for ordering the test, but providers need to be made aware of it (Yakovchenko et al., 2019). The first process was to provide education to the providers via a PowerPoint presentation during a regularly scheduled staff meeting. Provider education included use of the new EMR reminder (Appendix B), and general HCV education.

The provider education session was well received. It was comprised of a review of HCV including risks, prevalence, disease progression, and benefits of treatment. The roles of the PCP in HCV treatment were reviewed including the screening guidelines, importance of counseling on screening and risks, how to stage liver disease, when HCC surveillance is necessary, and how

to recognize extrahepatic manifestations. An overview of HCV treatment was provided including appropriate labs, available medications, and simplified treatment algorithms. Time was provided for questions.

Patient handouts were available in the lab and in exam rooms. Any patient being screened was to be given a handout that provided an overview of HCV and what the testing results mean (Appendix C/D).

Method

This QI study was a retrospective chart review. It allowed for evaluation of improvement using a PDSA cycle for three months, as compared to a three-month period prior to full implementation. De-identified data was extracted by LFMC IT staff; study data were collected and managed using REDCap electronic data capture tool hosted at UNM. Chart review was done globally for all providers for the designated three-month period. De-identified data was extracted from the LFMC EMR with queries for the number of patients seen who did not have prior documentation of HCV screening, number of screening tests done (HCV antibody), number of confirmatory tests (HCV viral load) done on positive antibody tests, and number of referrals for treatment made for those with documented viral load. Using Pearson's chi squared test and Fisher's exact test, a pre- and post-comparison was made. The pre- and post-populations were adults within the LFMC clinic who had not yet been screened for HCV, seen by LFMC providers. De-identified records were reviewed for the designated periods for lack of previous HCV testing done, and if HCV testing was done on that visit. The denominator was the number of eligible individuals (those without documentation of prior screening) seen during that time period without duplications, the numerator was the number of HCV screening tests done. The secondary comparisons made were those with positive antibody test getting confirmatory testing

done (viral load), and those with chronic HCV (positive viral load) who were referred for treatment.

Pearson's chi square (χ^2) test is an inferential statistical test used to determine whether two variables can be considered related "beyond a reasonable doubt", and to evaluate if the sample pattern is substantial enough so that it cannot be the result of sampling fluctuations. The null hypothesis states that there is no difference between the two sampled groups, and if that were true, the chi squared result would be zero (or close to zero). With one degree of freedom, a chi squared value of 3.841 is significant ($p = 0.05$). The greater the chi squared result, the stronger the significance level, indicating the observation is not random chance. Fisher's exact test is a similar test, also used for categorical data in a 2 by 2 table, when the cell numbers are less than five (Stommel & Dontje, 2014).

An improvement was defined as an increase in screening of eligible patients by 10%. Any increase in the number of confirmatory tests done and in the number of patients referred for treatment would be seen as an improvement. Study power was obtained for the pre- and post-screening rates only, using Pearson's chi squared test. The confirmatory and referral results were evaluated with Pearson's chi squared, or Fisher's exact test for cells less than 5. Power analysis statement: Assuming 4000 eligible patients in each time period and a baseline screening rate of 5%, this study will have sufficient statistical power (80%) to detect an increase in the proportion of screened patients using Pearson's chi squared test, if the intervention results in a screening rate of at least 6.5% (B. Boursaw, personal communication, January 31, 2021).

Barriers and Facilitators

PCPs are continually faced with challenges of negotiating numerous care priorities with limited time during patient visits. This process foreseeably required a few additional minutes of

education by the provider, but it is standard of care to offer the screening. Patients were free to decline the screening for any reason, but should make an educated decision to do so. Offering HCV screening during regularly planned visits should have facilitated the process by incorporating it into routine health care.

Prior to the COVID-19 pandemic, all patients were seen in person for HCV evaluation and treatment. During the COVID-19 climate, LFMC had adopted scheduling most patients as telehealth. This presented challenges in meeting face-to-face, in performing physical exams, and in assuring lab work was done. Telehealth can be appropriate for otherwise healthy individuals, and review of previous physical exam can be sufficient. It can lead to depersonalization of care though, as most patients being treated for HCV are established with other providers for their primary care, are being referred for treatment, and have most likely never met the HCV treating provider. For patients with advanced liver disease this is not adequate, and they should have an in-person exam. During the time of COVID-19, if a patient was not being seen in the clinic, (s)he would need to go to the clinic for a lab draw; this may have deterred some individuals from having it done. TH does have an advantage though: many patients can be treated for HCV by TH, but that is beyond the scope of this project.

Another barrier was that many patients who need to be screened for HCV have poor venous access due to past or present injection drug use. Having the rapid (finger stick) testing available can be of great benefit. It allows for results in 15 minutes, and confirmatory testing can be ordered right away instead of waiting for a send-out result and requiring the patient to return for another lab draw. Unfortunately, that test has not been available at LFMC and LFMC is not planning on making that test available.

Budget

The activities undertaken for this QI project were consistent with requirements of the UNM DNP program and were not billed to LFMC. The provider time allotted for the activity of training was consistent with patient care improvement requirements of LFMC. The only additional cost to the clinic was the cost of printing the handouts that were given to the patients during the screening. The cost of the handouts was \$7.00 per 100. There was no additional cost to the patient above what they would ordinarily pay for the clinic visit, and for the test if they were not insured or if they had a copay.

Timeline

The QI project was approved by the UNM College of Nursing and the UNM IRB on June 14, 2021. Provider education took place on July 7, 2021. After the training, data was extracted for a three-month period (July, August, September) for 2020, and again for 2021. Analysis was completed by December 31, 2021. The doctoral project was completed and defended on March 30, 2022.

This QI project served to standardize HCV screening within LFMC, educate providers about HCV, and improve the referral process by identifying patients with chronic HCV. Education of providers and patients plays a key role in improving this process. By maximizing the capabilities of our treatment team, we can have a more profound impact on the health of our patients, and on the long-term sequelae of HCV in our community.

Chapter 4 – Results

This chapter presents the results of the data analyses including comparison of number of eligible patients seen and screened during specified dates pre- and post-intervention. Data was obtained from the LFMC EMR in de-identified, number only form. The number of patients seen from July 1, through September 30, 2020 and July 1, through September 30, 2021 who had no evidence of HCV screening documented on their chart was obtained. Data was also obtained to reflect the number of screening tests that were done during the same time periods. For both years, those numbers were reviewed to determine how many of the screening tests were positive, and of those how many confirmatory tests (viral loads) were done. The number of positive viral loads was verified, as well as the number of referrals made based on those positive results.

Pre-intervention

From July 1, through September 30, 2020 5,329 patients were seen who did not have documented screening for HCV. 203 HCV screening tests were done, with 16 positive antibody tests resulted. There were nine confirmatory tests ordered, resulting in seven positive viral loads. five of those patients were referred for treatment.

Post-intervention

From July 1, through September 30, 2021 4,554 patients were seen who did not have documented screening for HCV. 531 HCV screening tests were done, with 23 positive antibody tests resulted. There were nine confirmatory tests ordered, resulting in seven positive viral loads. six of those patients were referred for treatment.

Preliminary Analyses and Findings

The number of patients seen who did not have documentation for previous HCV screening during both time periods, and number of HCV screening tests done during both time

periods were evaluated using Pearson's chi squared. The percent of positive antibody tests and percent of confirmatory tests were also evaluated using Pearson's chi squared. The percent of positive viral loads and referrals made were evaluated using Fisher's exact test. Pearson's Chi square and Fisher's exact tests were done using GraphPad Prism version 9.3.0 for Windows, GraphPad Software, San Diego, California USA, www.graphpad.com.

The number of patients screened for HCV significantly increased after the intervention. $\chi^2(1, 9,883) = 220.13, p < 0.0001$. It can be concluded that there was a positive relationship for the number of patients screened after the interventions took place, compared to the prior year.

In 2020, 5329 patients were seen who did not have previous documentation for HCV screening. 203 HCV screening tests were done, which is a screening rate of 3.8%. In 2021, 4554 patients were seen who did not have previous documentation for HCV screening. 531 HCV screening tests were done, which is a screening rate of 11.7%. There was an improvement of 7.9 percentage points, which reflects a 3-fold increase in the amount of testing done ($\chi^2 = 220.13, p < 0.0001$). The percentage of positive antibody tests was lower in the post-intervention period (7.9% versus 4.3%), but was not statistically significant, $\chi^2(1, 734) = 3.68, p = 0.06$. The percentage of confirmatory tests ordered was also lower post-intervention (56% versus 39%), but was not statistically significant, $\chi^2(1, 39) = 1.11, p = 0.29$. The percentage of positive viral loads was identical pre- and post-intervention, (78%, $p > 0.99$). The percentage of referrals made was improved post-intervention (71% versus 86%, $p > 0.99$); this was not statistically significant, but it did meet the project goal of improving.

Evaluations and Outcomes

In 2021, post-intervention, there were fewer patients seen who did not have documentation of previous testing, but there were significantly more screening tests ordered. It

can be assumed that providing provider education improved the provider screening behavior, though these results are still very far from the universal screening recommendation. The percentage of positive antibody tests was lower, but this corresponded with previous studies that increase the number of eligible individuals being screened by encouraging universal screening (Konerman, et al., 2017). There was a decrease in the percentage of confirmatory tests done, but it is unclear why. It could be due to the current COVID-19 pandemic or to provider turnover, it will be discussed further in the discussion chapter. The percentage of positive viral loads was unchanged. The number of individuals referred for treatment was improved and met the project goals, but the low numbers did not provide for significance.

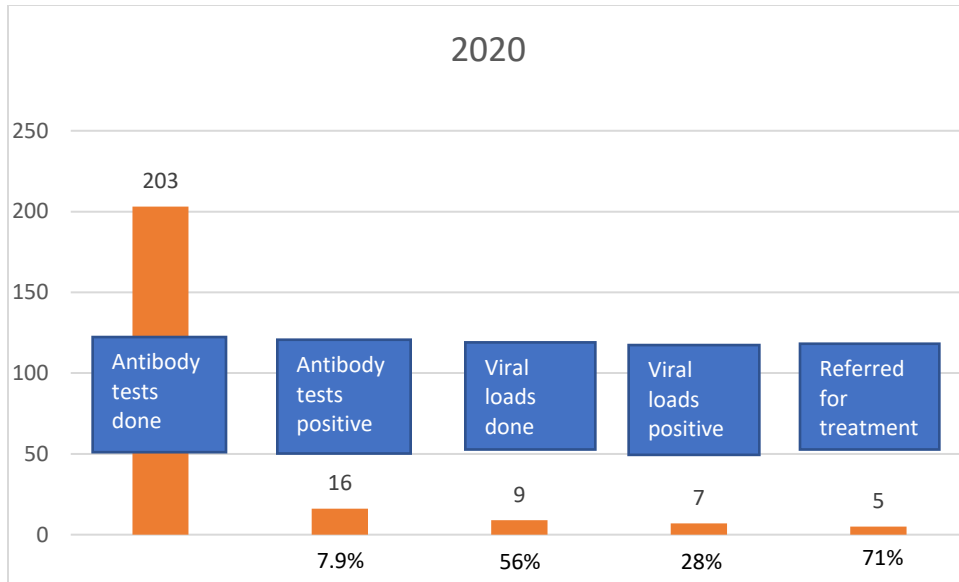


Figure 1 2020: Number of HCV antibody screening tests done, numbers and percentages of positive antibody tests, viral loads done, positive viral loads, and patients referred for treatment

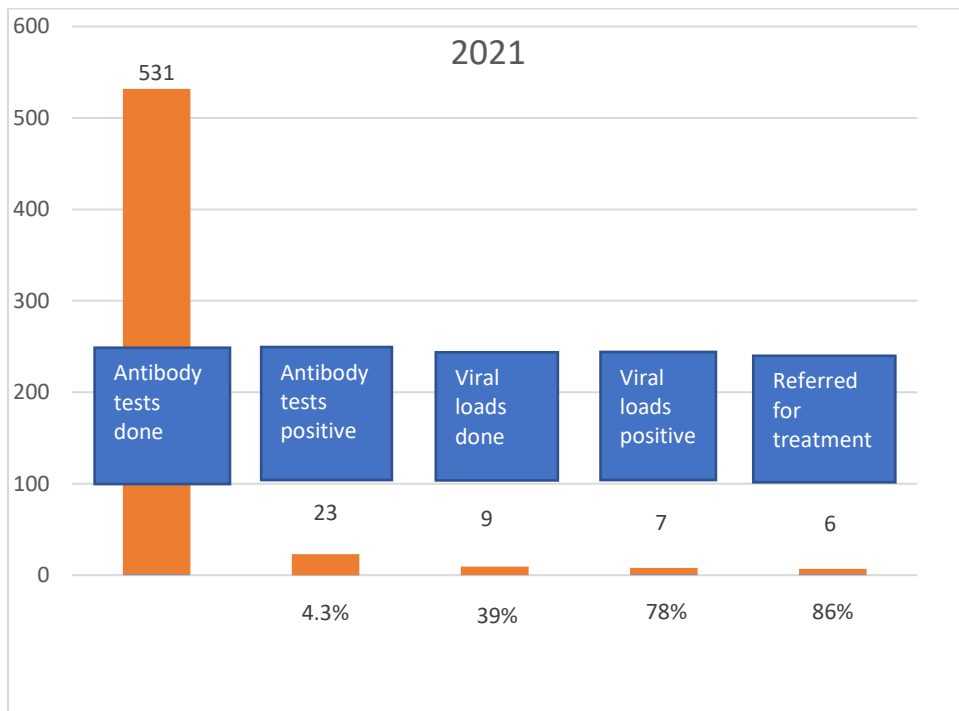


Figure 2 2021: Number of HCV antibody screening tests done, numbers and percentages of positive antibody tests, viral loads done, positive viral loads, and patients referred for treatment

Chapter 5 – Discussion

This quality improvement project, using quantitative methods, sought to assess improvement of Hepatitis C screening, confirmation, and referral for treatment within La Familia Medical Center by implementing a reminder in the EMR and providing education to providers and patients.

Key Findings

The findings demonstrated an improvement in provider behavior in ordering screening tests, but there was not significant improvement in confirmatory tests done, or in referrals made. The outcomes of this project indicate that adding an EMR reminder and providing provider education is an effective approach to increase the number of patients screened for HCV.

A surprising finding was the decrease in number of confirmatory tests done. One of the factors that could influence this result is a recent increase in provider turnover. During July through September 2021, LFMC had a turnover of five of 14 providers. These providers were present for the educational session, but left the organization prior to completion of the three-month evaluation period. This may have led to lack of follow-up, and it placed an additional burden on the remaining providers until new providers were brought in and oriented to the LFMC system. Another factor could be the current COVID-19 environment, which presented barriers to being seen in the clinic and having further testing done, but COVID-19 was also present during the previous data collection period. Perhaps the recent COVID-19 variants affected personal behavior and mobility, but investigation of that was beyond the scope of this project.

The Model for Improvement using a PDSA cycle was helpful in integrating this quality improvement project. The project aim was to increase the number of eligible patients screened

for HCV, have confirmatory testing done if antibody positive, and have a referral for treatment in place if chronic HCV was present. An improvement was defined as an increase in screening by 10% over a three-month period, an overall increase in confirmatory testing, and referral for treatment if virus was present.

A significant increase in HCV screening tests was seen post-intervention, from 3.8% of eligible patients screened during the 2020 period to 11.7% during the 2021 period. This is an improvement of 7.9 percentage points; a three-fold increase in the amount of screening done. The decrease in antibody positivity rate is likely due to the increased screening (universal versus risk-factor focused) and has been seen in previous studies that sought to implement universal HCV screening. When universal screening is implemented, it includes not only those at increased risk of HCV infection but also those with low or average risk. This often leads to a decrease in the positivity rate (Konerman et al., 2017; Zuckerman et al., 2017). It is not clear why there was a decrease in the number of confirmatory tests done, but as discussed previously it may be due to increased provider turnover and the current COVID-19 variant environment.

The lack of confirmatory testing should be much less of an issue going forward as LFMC has recently adopted an HCV lab test that includes reflex testing. This new test has been available through Tricare since December 15, 2021; it provides for reflex viral load (confirmatory testing) with the same blood draw if the antibody is present. Use of reflex testing has been shown to significantly improve diagnosis rates and to decrease omitted viral load testing up to 76%. It requires fewer provider visits and fewer blood draws (Lopez-Martinez et al, 2020). LFMC contracts with Tricare for laboratory services. which provides the new HCV antibody and reflex test (HCVDX). The cost of the test is covered through insurance, but for those without insurance the cost is \$14.25 for the antibody portion, and an additional \$215.85 if

the reflex test is done. This can be cost prohibitive for an uninsured patient, so some providers will still opt to order the basic HCV antibody test, which costs \$18.00 (I. Martinez, personal communication, January 25, 2022).

This project reflects the improvement in screening that was observed by Konerman et al. (2017) and Miller et al (2016) when they implemented an EMR prompt for HCV screening. The EMR reminder in the LFMC system was introduced a couple of months prior to the provider education session, but providers were largely unaware of it. Providing education to the providers seemed to increase the number of screening tests done, as was also shown by Miller et al. and Gemelas et al (2016). All of the studies that tracked patients through a treatment cascade showed a significant drop-off of patients along each step of the cascade, but the lack of confirmatory testing seen here post-intervention was the most significant. None of the studies reviewed had automatic reflex testing for HCV confirmation, and it will be interesting to see going forward how this is affected. As Gemelas et al. reported, the higher screening rate also allows the clinic to have a better understanding of the disease burden in the community.

Implications

The current recommendation from the USPTF, CDC and AASLD is to screen all patients age 18 to 79 for HCV once (annually for those with risk factors). This project demonstrated that more patients can be screened when providers are informed of current guidelines, recommendations and treatment regimens. Providers face constant challenges in providing recommended screenings, but having a reminder in the EMR can reinforce current recommendations. The recently updated option to order the diagnostic HCV testing, which includes the reflex viral load when the antibody is positive, will decrease the number of patient

visits and lab draw orders. This should improve the number of confirmatory tests done and simplify movement along the treatment cascade.

With the recent increase in provider turnover, new providers should be educated on the current screening recommendations, and on accessing the patient screening prompts in the EMR. New providers should be aware of on-site availability of HCV treatment and the referral process. Maintaining this standard of care can have meaningful implications for patient health and community health.

The policies of LFMC should be continually updated to include the standard of care. In particular, updates should include the changes in reflex testing, and program availability for patients who are not eligible for insurance (specifically the undocumented).

Future Research

This QI project was done during a time of COVID-19, and prior to availability of reflex testing. If COVID-19 ever becomes a non-issue, it would be interesting to assess improvement of diagnosis and movement along the treatment cascade. Recent research by Lopez-Martinez et al. (2020) has shown significant improvement in diagnosis of chronic HCV with reflex testing. With the current low confirmatory testing numbers, it would be helpful to assess if the use of reflex testing increases the number of individuals diagnosed with chronic infection.

One factor in ordering HCV testing is lack of patient insurance. Looking at whether providers neglect to order tests due to lack of insurance would be a helpful indicator moving forward. DOH has options for HCV screening that will not incur patient cost, but LFMC is not accessing those programs. Closer partnership with DOH may avail LFMC to those programs, and improve patient screening especially for those not eligible for insurance coverage.

Sustainability of Practice Change

Providers who were employed at the time of the educational intervention were informed on current recommendations, standards of care, treatment protocols, and the EMR prompt. New providers should be updated on this as well, and a presentation is being scheduled for new residents coming into LFMC. Universal screening is standard of care, and the hope is that this program will continue to improve compliance.

LFMC currently has an HCV treatment team, but only one provider who offers treatment. All providers have been offered treatment training, but there has not been uptake with the current providers. It is important to have a treatment champion within the clinic for consultations and recommendations, and LFMC does plan to continue that position. With the new simplified treatment algorithms, it is the hope that more providers will be amenable to provide treatment. A limitation of this project is that it focuses on early components the HCV care cascade with screening, confirmation, and referral to treatment. It does not include treatment. Within these parameters, it is the hope that providers will continue to improve on the universal screening goals. It is reasonable to envision annual updates and reminders on HCV screening and treatment, as it is a quality measure within LFMC. Once a patient has been diagnosed, (s)he can typically be scheduled with the treatment provider within 2 weeks. If the current treating provider would not be available, LFMC would need to find another treating provider.

Limitations

There were several limitations to this study. Most retrospective studies evaluated data for a one- to three-year period, this study evaluated data for only three months. This QI project was done within a three-clinic FQHC that serves a population that is largely Latino and in an underserved community. It was also done during the COVID-19 pandemic, which has resulted in limited clinic access and patient mobility. The relatively low antibody positivity rate could be

related to selection of individuals being screened, i.e., screening may not have been ordered if the patient was uninsured (which was not evaluated in this study). Another limitation was the unexpected increase in provider turnover during the 2021 evaluation period.

This study could be generalized to FQHCs that serve a similar population. Data collection was felt to be valid, as it was done by one person with standardized measurements. Data was analyzed using a validated tool, with the guidance of a statistician.

Conclusion

Chronic HCV is a potentially devastating disease that is easily treated when it is caught early. Because it frequently does not have symptoms early on, universal screening of all adults is an effective way to identify asymptomatic patients. Vigilant monitoring of all birth cohorts, including the younger cohorts that have had increased incidence of chronic HCV, will help us meet the Healthy People 2030 goal of eliminating HCV as a public health problem. Improvement in accurate and comprehensive reporting trends in population-based screening are warranted to help us meet that goal (Bian, J, & Schreiner, A., 2019).

The outcomes of this project reinforce the importance of keeping providers up to date on current screening recommendations and availability of effective treatments. Only in identifying individuals infected with chronic HCV and treating them before complications arise, can we have a significant impact on this public health problem.

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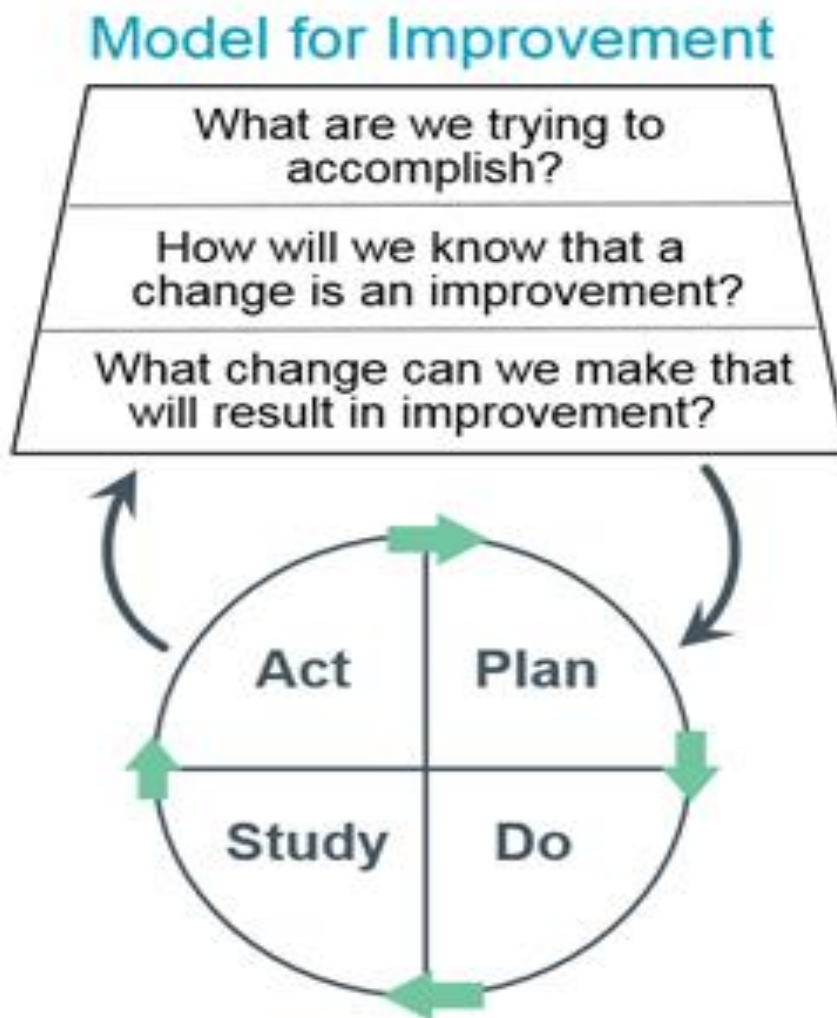
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Appendix A

Theoretical Model Diagram



Appendix B

EMR reminder

CDSS TESTPATIENT, Test Upgra... Jan 1, 1987 (35 yo F) Acc No. T-52171

TestPatient, Test 35Y, F 01/01/1987 508-329-3337 112 TURNPIKE RD, WESTBOROUGH, MA 01581-2804 ayoung@lfmctr.org

All CDSS Practice Configured Registry Dental

My Alerts Only HM Patient Specific Alert

Alert	Last Done	Freq	Due Date	Orders	Status
CDSS Alerts					
Body Mass Index		24M	02/05/2022		
HIV screening		0M	02/05/2022	OS LF HIV Screening	
Influenza vaccine (over 50)		6M	02/05/2022	OS LF FLU adult 2020-2021	
Smoking status		12M	02/05/2022	OS LF Tobacco Use	
Practice Configured Alerts					
BMI assessment & Counseling Adult		-	02/05/2022		
Hepatitis C Viral Test: Ever		-	02/05/2022		
HPV test 30-65 yrs (Must have PAP also)		-	02/05/2022		
PAP test 30-65 (Must have HPV also)		-	02/05/2022		
SBIRT / Depression screen		-	02/05/2022		
Registry					
This patient does not meet the specified criteria for any Registry alerts.					
Dental					

Print Close

Appendix C

Patient Handout – English

Hepatitis C Testing

What to Expect When Getting Tested

All adults, pregnant women, and people with risk factors should get tested for hepatitis C.

Most people who get infected with hepatitis C virus (HCV) develop a chronic, or lifelong, infection. Left untreated, chronic hepatitis C can cause serious health problems, including liver damage, cirrhosis, liver cancer, and even death. People can live without symptoms or feeling sick, so testing is the only way to know if you have hepatitis C. Getting tested is important to find out if you are infected so you can get lifesaving treatment that can cure hepatitis C.

Getting tested for hepatitis C

A blood test, called an HCV antibody test, is used to find out if someone has ever been infected with the hepatitis C virus. The HCV antibody test, sometimes called the anti-HCV test, looks for antibodies to the hepatitis C virus in blood. Antibodies are chemicals released into the bloodstream when someone gets infected.

Test results can take anywhere from a few days to a few weeks to come back. Rapid anti-HCV tests are available in some health clinics and the results of these tests are available in 20 to 30 minutes.

What does a non-reactive HCV antibody test result mean?

- ➔ A **non-reactive** or negative antibody test means that you are not currently infected with the hepatitis C virus.
- ➔ However, if you think you might have been exposed to hepatitis C in the last 6 months, you will need to be tested again.

What does a reactive HCV antibody test result mean?

- ➔ A **reactive** or positive antibody test means you have been infected with the hepatitis C virus at some point in time.
- ➔ Once people have been infected, they will always have antibodies in their blood. This is true if they have cleared the virus, have been cured, or still have the virus in their blood.
- ➔ A reactive antibody test **does not** necessarily mean that you currently have hepatitis C and a follow-up test is needed.

What to do if the HCV antibody test is reactive

- ➔ If the antibody test is reactive or positive, you need an additional test to see if you currently have hepatitis C. This test is called a nucleic acid test (NAT) for HCV RNA. Another name used for this test is a PCR test.
- ➔ If the NAT for HCV RNA is:
 - **Negative** - you were infected with hepatitis C virus, but the virus is no longer in your body because you were cured or cleared the virus naturally.
 - **Positive** - you now have the virus in your blood.
- ➔ If you have a **reactive** antibody test and a **positive** NAT for HCV RNA, you will need to talk to a doctor about treatment. Treatments are available that can cure most people with hepatitis C in 8 to 12 weeks.



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April 2020

Appendix D

Patient Handout – Spanish

Análisis para detectar la hepatitis C

Qué esperar al hacerse el análisis

Todos los adultos, las mujeres embarazadas y las personas con factores de riesgo deben hacerse análisis para detectar la hepatitis C.

La mayoría de las personas que se infectan con el virus de la hepatitis C (VHC) desarrollan una infección crónica o de por vida. Si no se trata, la hepatitis C crónica puede provocar problemas de salud graves, como daño hepático, cirrosis, cáncer de hígado e incluso la muerte. Las personas pueden vivir sin tener síntomas o sentirse enfermas, por lo que el análisis es la única manera de saber si tiene hepatitis C. Hacerse el análisis es importante para averiguar si usted está infectado y así poder recibir un tratamiento que pueda salvar la vida capaz de curar la hepatitis C.

Hacerse el análisis para detectar la hepatitis C

Para averiguar si una persona se infectó alguna vez con el virus de la hepatitis C, se usa un análisis de sangre llamado prueba de detección de anticuerpos contra el VHC. La prueba de detección de anticuerpos contra el VHC, a veces llamada prueba anti-VHC, busca anticuerpos contra el virus de la hepatitis C en la sangre. Los anticuerpos son sustancias químicas que se liberan en el torrente sanguíneo cuando alguien contrae una infección.

Obtener los resultados de la prueba puede tardar entre unos días y unas semanas. En algunas clínicas médicas, existen pruebas anti-VHC rápidas, y los resultados de estas pruebas están disponibles entre 20 y 30 minutos.

¿Qué significa un resultado no reactivo en la prueba de detección de anticuerpos contra el VHC?

- Una prueba de detección de anticuerpos **no reactiva** o negativa significa que usted no está infectado actualmente con el virus de la hepatitis C.
- Sin embargo, si cree que podría haber estado expuesto a la hepatitis C en los últimos 6 meses, necesitará hacerse la prueba nuevamente.

¿Qué significa un resultado reactivo en la prueba de detección de anticuerpos contra el VHC?

- Una prueba de detección de anticuerpos **reactiva** o positiva significa que usted se ha infectado con el virus de la hepatitis C en algún momento.
- Una vez que las personas se han infectado, siempre tendrán anticuerpos en la sangre. Esto es así ya sea que hayan eliminado el virus, se hayan curado o sigan teniendo el virus en la sangre.
- Una prueba de detección de anticuerpos **reactiva no** necesariamente significa que usted tiene hepatitis C actualmente y que es necesaria una prueba de seguimiento.

Qué hacer si la prueba de detección de anticuerpos contra el VHC es reactiva

- Si la prueba de detección de anticuerpos es reactiva o positiva, necesita hacerse otra prueba para ver si tiene hepatitis C actualmente. Esta prueba se llama prueba de ácido nucleico (nucleic acid test, NAT) para detectar el ácido ribonucleico (ARN) del VHC. Otro nombre que se usa para esta prueba es prueba de reacción en cadena de la polimerasa (polymerase chain reaction, PCR).
- Si la NAT para detectar el ARN del VHC es:
 - **Negativa:** usted se infectó con el virus de la hepatitis C, pero el virus ya no se encuentra en el cuerpo porque se curó o eliminó el virus de forma natural.
 - **Positiva:** usted tiene el virus actualmente en la sangre.
- Si su prueba de detección de anticuerpos es **reactiva** y su NAT es **positiva** para el ARN del VHC, deberá hablar con un médico sobre el tratamiento. Hay tratamientos disponibles que pueden curar a la mayoría de las personas con hepatitis C en 8 a 12 semanas.



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