Hepatitis C Treatment at a Rural Navajo Health Clinic Using Project ECHO

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Abstract

Purpose: Hepatitis C incidence is higher among American Indian/Alaskan Native populations than any other racial or ethnic group in the United States. Chronic Hepatitis C complications include cirrhosis of the liver, end stage liver disease, and hepatocellular cancer. Direct acting antiviral treatment taken orally results in ≥ 90% cure, yet rural primary care providers lack the training and confidence to treat and monitor patients with chronic Hepatitis C. Rural patients are reluctant to travel to urban areas for Hepatitis C treatment. Project ECHO is an innovative tele-mentoring program where specialists mentor primary care providers via videoconferencing to treat

diseases they would otherwise be unable to manage. The purpose of this quality improvement project was to increase Hepatitis C treatment at a rural Navajo health clinic through partnership with Project ECHO specialists.

Methods: This quality improvement project was guided by Lippitt's Phases of Change Theory. The systematic process plan included a protocol for roles and expectations of all members of the healthcare team, a documentation and communication plan, and a tracking system for monitoring patient progress through the plan of care. Outcomes were analyzed by descriptive statistics.

Findings: Following partnership with Project ECHO, six patients (31.6%) consented to receiving Hepatitis C treatment at the rural Navajo health clinic. All six were contacted by outreach staff at multiple points during the project. Five (26.3%) completed the full course of drug therapy. Four (21.1%) completed follow-up lab work, of which three (15.8%) had a documented cure by sustained virologic response.

Conclusions: Hepatitis C care via Project ECHO-rural clinic partnership was affordable, feasible and not excessively time consuming for a facility with substantial patient outreach resources.

Key words: Rural health clinic, Hepatitis C, Project ECHO, tele-mentoring, Native American

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The Hepatitis C Virus (HCV) invades the liver and causes inflammation (American Association for the Study of Liver Diseases-Infectious Diseases Society of America [AASLD-IDSA], 2018). According to the Centers for Disease Control and Prevention (CDC, 2016), HCV is responsible for more deaths than all other reportable infectious conditions combined. HCV mortality is estimated at 4.45 deaths per 100,000 persons, and an estimated 3.5 million people in

the United States live with chronic HCV (CDC, 2016). Possible consequences of chronic HCV include cirrhosis of the liver, end stage liver disease, and hepatocellular cancer (Thornton, 2015).

The incidence of HCV is higher in American Indian and Alaskan Native populations than in any other racial or ethnic group (CDC, 2016). American Indian and Alaskan Native populations had a reported HCV incidence of three cases per 100,000 people; while the white, non-Hispanic ethnic group had an incidence of one case per 100,000 people (CDC, 2016). There are an estimated 23,000 to 55,000 chronic cases of HCV infection in the State of New Mexico (New Mexico Hepatitis C Coalition, 2016). This represents 1.10% to 2.63% of the total population in New Mexico, estimated at 2,088,070 (United States Census Bureau, 2017).

Given the possibility of grave consequences from untreated HCV, timely expert care is essential in management of this disease (AASLD-IDSA, 2018). Since 2013, direct acting antiviral treatment has been available, which is taken orally and has a cure rate greater than 90% (Department of Health and Human Services [DHHS], 2017). With current medications, most cases require eight to twelve weeks of daily medication and few side-effects are reported (DHHS, 2017; Project ECHO, 2018b).

The Alamo Navajo Reservation is located in a rural area of Socorro County, New Mexico. At the most recent census, 2,006 people were living in the Alamo chapter of the Navajo Nation (Navajo Division of Health & Navajo Epidemiology Center, 2013). According to the United States Department of Agriculture (USDA, 2019), the Rural-Urban Commuting Area Codes (RUCA) classify census tracts by population density, commuting patterns, and area urbanization. The census tract that includes the Alamo Navajo Reservation received a 2010 RUCA code of 10 and had a calculated population density of 3.3 people per square mile (USDA, 2019). To illustrate the

rural nature of this community, the nearest grocery store is approximately a one-hour drive from the center of Alamo.

The Alamo Navajo Health Center or "Alamo Clinic" is located at a two-hours' drive from the nearest healthcare facility currently accepting referrals for HCV treatment. The clinic and community, therefore, are not only rural but also isolated from necessary healthcare services (Alamo Navajo Chapter, 2018). Prior to this project, patients had to receive a referral for further care, as there were no providers trained to treat HCV available at the Alamo Clinic. Additionally, the community health nurse at the Alamo Clinic observed issues with follow through on referred treatment, as evidenced by only one individual in the community having been successfully treated for a chronic HCV infection (T. Winchester, personal communication, July 2018). This individual was a pediatric patient taken to the regional health center by a parent. None of the 19 adults in the community who were known by the Alamo clinic to have HCV had followed through on receiving treatment with specialists at the regional medical center (T. Winchester, personal communication, July 2018).

In 2003, Dr. Sanjeev Arora developed Project Extension for Community Health Outcomes (ECHO) while working at the University of New Mexico Health Sciences Center (UNMHSC) to address the needs of rural communities and underserved populations facing growing incidence of HCV infections. Project ECHO has demonstrated efficacy in bringing the necessary level of care to rural areas such as the tribal health clinic for which this project is intended (Arora et al., 2014). Project ECHO is an innovative tele-mentoring program where specialists mentor primary care providers via videoconferencing to treat diseases they would otherwise be unable to manage (Arora et al., 2010). Arora et al. (2010) assert that with the support of Project ECHO, HCV care provided by rural primary care providers has the potential to be equal in quality to the care provided at

academic medical centers. A systematic review by Zhou et al. (2016) assessed patient and provider outcomes of Project ECHO across 39 studies, including four studies on HCV treatment, and concluded that patient outcomes were comparable between facilities using Project ECHO and care provided in a specialist's office.

Background

Two options were available to provide HCV treatment services for the population served by the Alamo Clinic. One option was to provide patients with a referral to a specialist at a regional medical center located at a minimum of 85 miles and up to 135 miles distance from the clinic, depending on whether the unpaved portion of the shorter route is passable. This option was previously tried and resulted in only one pediatric patient receiving treatment for HCV. No adults travelled to receive treatment. The second option, using Project ECHO, was chosen to support the family practice clinic to provide HCV treatment in this rural setting. Project ECHO established a base of evidence and established tele-mentoring procedures to enable safe HCV care for patients and a positive experience for family practice providers (Zhou, et al., 2016). Project ECHO was considered a logical fit for the Alamo Clinic.

A literature review of the available evidence on Project ECHO was conducted and provided an assessment of Project ECHO including valuable evidence on: quality of care provided with the ECHO model (Arora et al., 2011), professional experience of providers using ECHO (Dubin et al., 2015; Fisher et al., 2017; Pindyck et al., 2015), likelihood patients in rural areas would receive needed care (Carey et al., 2016), and financial acceptability of increasing care for HCV (Rattay et al., 2017). The strongest single study evidence for Project ECHO's HCV treatment program was conducted by Arora et al. (2011). This study provided the rare example of a control group, as most literature identified on Project ECHO surveyed only one cohort of healthcare providers. This study

established that care given at ECHO sites was equal to care given in an academic medical center by comparing patient outcomes such as sustained virologic response (SVR) and serious adverse events (SAE).

Rural facilities such as the Alamo Clinic have recognized the need for an increased specialized care support network for providers. Project ECHO demonstrates decreased professional isolation, increased professional support, increased access to specialty consultation, and resulted in valuable feedback from specialists (Dubin et al., 2015; Fisher et al., 2017; Pindyck et al., 2015). Additionally, the program was designed to meet the needs of underserved communities and to address health disparities such as those observed in this tribal health center (Project ECHO, 2018a). At the UNMHSC Project ECHO hub, tele-mentoring services are provided at no cost to family practice clinics. No facility agreement is needed, however provider training at the Project ECHO hub is recommended. Site visits are available to assess facility needs.

Though not specifically assessing Native American communities, one article identified access to care for individuals in rural areas, which is an accurate descriptor for the Alamo Navajo Reservation. Carey et al. (2016) assessed the likelihood a patient would receive needed services based on the distance they had to travel. The authors found that living in a rural area decreased the likelihood a patient would access specialty care by 22%, yet only decreased the likelihood of accessing ECHO care by 2%. This illustrates patient acceptability of alternative modes of care in rural or remote locations such as the Alamo Clinic.

From an organizational and governmental perspective, a barrier to healthcare is often financial. In the United States the amount government and insurance payors see as acceptable for expensive medical treatments is frequently set at $50,000 to $100,000 per quality adjusted life year (QALY) gained (AASLD-IDSA, 2017). In other words, an individual must be expected to gain

one year of life in good health condition (National Institute of Health and Care Excellence, 2018). Rattay et al. (2017) found that in 95.6% of cases, treatment of HCV costs less than $50,000 per QALY. This indicates that treatment of HCV is of acceptable financial value according to established limits and indicators.

Purpose and Theoretical Framework

The purpose of this quality improvement project was to develop, implement, and evaluate a systematic process plan for the use of Project ECHO to treat patients for HCV at the Alamo Navajo Health Center. Lippitt's Phases of Change Theory (Lippitt et al., 1958) was used as a guide to the process of implementing this proposed change in services at the Alamo Clinic. Lippitt's Phases of Change Theory is a seven-step framework that focuses on the responsibilities of the change agent (Kritsonis, 2005). See Table 1 for a description of how the framework guided this project through the implementation phases. In this project, the change agent was represented by the quality improvement Project Manager.

Table 1

Lippitt's Phases of Change Theory as a Guide to the Quality Improvement Process

Phase of Change	Steps in the Quality Improvement Process
1. Diagnose problem	Problem outline: Alamo Clinic staff were concerned about the growing number of their patients who were positive for HCV. Patients were not choosing to travel for two hours to receive HCV care from the nearest specialist. The Alamo Clinic wanted to improve access to HCV care by providing treatment onsite with tele-mentoring support of specialists with Project ECHO.
2. Assess motivation & capacity for change	Motivation: Alamo clinic management held long-standing discussions about the possibility of connecting with the tele-mentoring services of UNMHSC's Project ECHO for Hepatitis C.

	The medical director requested a dedicated change agent to develop the process and procedures in order for the Alamo Clinic to be successful at integrating Project ECHO tele-mentoring with local HCV care. Barriers: Uncertainties remained about funding clinic support staff and the potential cost of HCV medication. The top two reasons given by stakeholders for lack of progress in integrating HCV care with Project ECHO were unassigned administrative needs for tracking patients and potential breakdown in communication with the high volume of temporary providers in this rural clinic. Capacity: Project ECHO was available free of charge. Internet access and web cameras were already available onsite. The clinic's pharmacist was interested in ordering the necessary medication. The CHR and BHL were enthusiastic about supporting outreach efforts to provide HCV treatment locally.
3. Change agent's motivation & resources	HCV is a disease affecting many patients with whom the Project Manager has worked for several years. Improving access to HCV care in a meaningful way to this rural population by offering treatment at the Alamo Clinic was the primary motivation.
4. Select progressive change objective	The overall goal was to improve HCV treatment in the local population. In order to meet this goal, the objective of this quality improvement project was to develop functional processes and procedures to ensure success in integrating Project ECHO tele-mentoring with the needs of the Alamo Clinic staff.
5. Choose appropriate role for change agent	The Project Manager facilitated connection to Project ECHO, use of their resources, and developed the roles and procedures of the clinic healthcare team to begin providing HCV care at the clinic.
6. Maintain change	After tele-mentoring with Project ECHO, the medical director felt comfortable providing HCV care for patients using the online resources from Project ECHO. Tele-mentoring continues to be available for consultation for complicated cases. The CHR and BHL continue to contact patients in need of testing and care.

7. Terminate the helping relationship	The Project Manager is no longer present at this facility. The pharmacist, CHR and BHL continue to coordinate with the medical director to provide HCV care.

Lippitt's Phases of Change Theory was chosen as the framework to guide this quality improvement project because it provides a clear, detailed approach to planned change. In a comparable example, Manyibe et al. (2015) used this framework in a program to enhance research capabilities of faculty in minority serving institutions through a peer mentorship program. This bears similarity to this project as it did address Native American institutions and was a peer mentorship program to enhance skills of those working in underserved areas.

The systematic process plan developed in this quality improvement project included a protocol for roles and expectations of all members of the healthcare team, a documentation and communication plan, and a tracking system for monitoring patient progress through the plan of care. The primary objective was for patients to receive HCV treatment at the Alamo Clinic where they are more likely to complete the course of treatment, rather than by referral to UNMHSC that would involve traveling two hours away from home. The systematic process plan was evaluated for success in meeting this primary objective for a period of six months. This project was approved by the New Mexico State University Institutional Review Board, Study # 17430; the Acting Health Services Director of the Alamo Navajo Health Center; and by the Alamo Navajo Board President.

Method

This quality improvement project established a process for providing HCV care at the Alamo Clinic for patients between the ages of 18 and 65. The focus of the intervention was on the workflow for the five healthcare providers, community health representative (CHR), behavioral health liaison (BHL), and clinic nurse. A CHR is an unlicensed person trained to help with patient

outreach, education and transportation. A BHL is a licensed or unlicensed person with similar training as a CHR, with an additional focus on patients with behavioral or mental health needs.

The following protocol was developed in consultation with key stakeholders representing the providers and the staff of the Alamo Clinic. To provide treatment for these patients in the way that was most efficient yet also ensured quality, all five providers at the clinic were authorized to discuss potential HCV treatment with the patient and order confirmatory HCV testing. Managing treatment of HCV, however, was tasked to the medical director. This close monitoring of patients with HCV was considered important in ensuring quality care, as the remainder of the providers on staff were only on short term contracts with the Alamo Clinic.

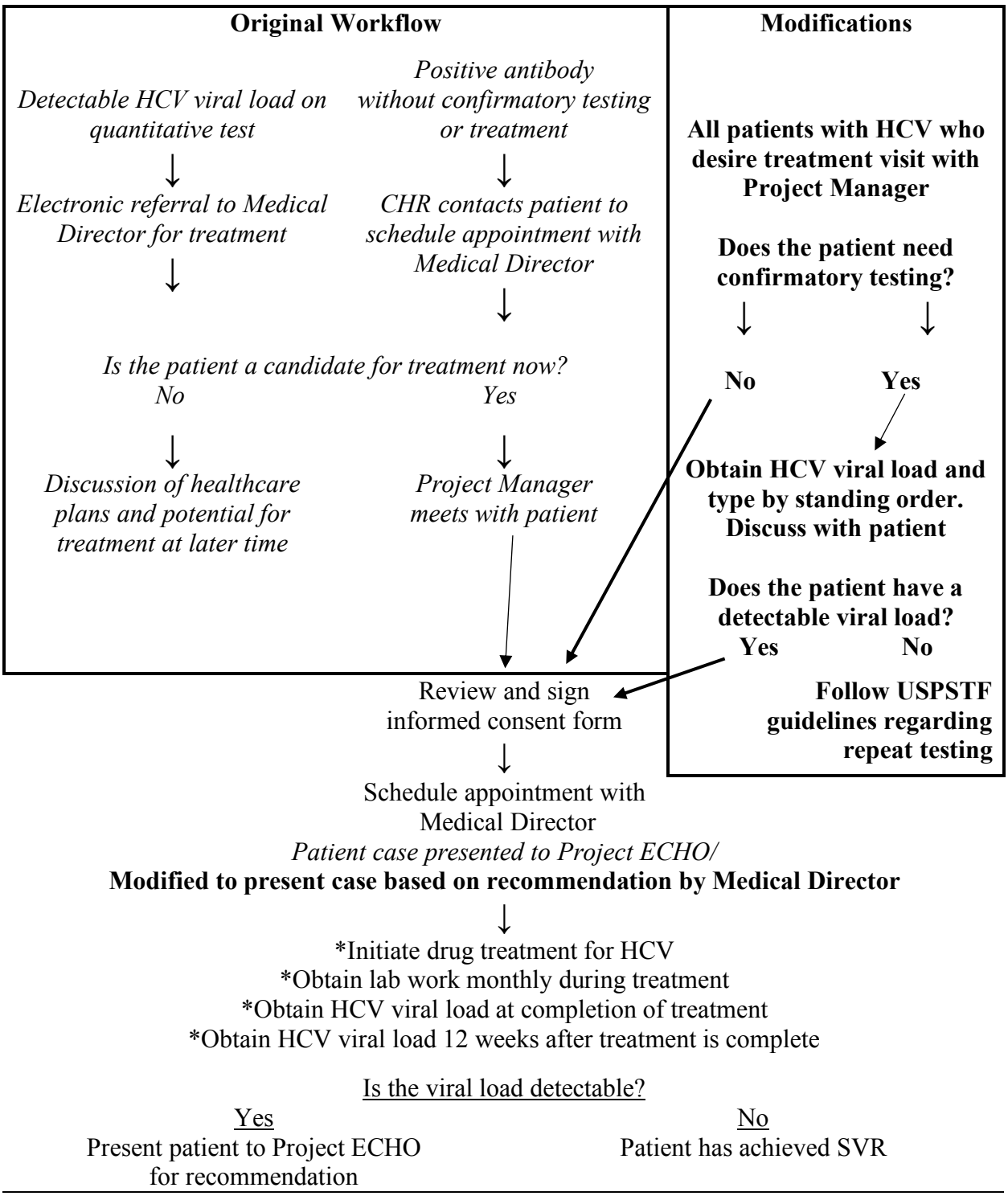
Project Steps

Step 1: December 2018, the CHR began contacting patients with active HCV infections for follow-up appointments with the medical director to discuss treatment.

Step 2: Once all pre-treatment lab work was completed, the first two patients were presented to Project ECHO for treatment recommendations. It was initially expected that all patients would need to be presented, but it quickly became apparent to the medical director that he was confident in following the treatment algorithms, which are provided free of charge by Project ECHO, for all patients without complications such as cirrhosis, kidney disease or other special medical concerns. Figure 1 outlines the original planned workflow for the project process steps, and the modifications in process steps that were made during the project.

Figure 1

Project Workflow with Modifications in Practice Made During the Project.



Note. *Indicates points in treatment plan for CHR or BHL to contact patient.

One additional patient was presented for concerns over comorbid conditions prior to initiation of treatment. After the patient was deemed appropriate for treatment, the pharmacy began the process of ordering medication and obtaining approval from the patient's insurance carrier. All patients had access to medications without financial burden.

Step 3: Patients were tracked throughout the process of treatment by using the NICE Hep C Patient Management tool Excel spreadsheet available at the Northern Tier Initiative for Hep C Elimination (NICE) project (Gazarian & Owen, n.d). Once a patient was determined to have a sustained virological response, then they were discharged from the HCV patient cohort (U.S. Department of Veteran Affairs, 2015). Patients who did not complete follow-up lab work on schedule were contacted in person and by phone by the CHR or the BHL.

Measures

Project process measures were chosen to assess both the workflow for HCV care in the primary care clinic and the effectiveness of the workflow in assisting patients to enter and complete HCV treatment. Of patients entering HCV treatment, the goal was for 65% to be presented to Project ECHO. Most HCV patients were known to the CHR or BHL as members of the community and likely to be located, therefore a goal of 75% contact success was set. Contact success was defined as achieving direct communication with the patient, either by phone or in person.

Patient outcome measures included:

- evaluation of the percent of HCV patients entering treatment who were presented to Project ECHO,
- percent of those who completed the full course of drug therapy,

- percent who completed lab work at or after 12 weeks post therapy, and
- percent of those who achieved a cure.

"Cure" was defined as a sustained virologic response (SVR), determined by lab work as undetectable levels of the HCV in a patient's blood after a 12-week period following completion of drug treatment (AASLD-IDA, 2018).

Results

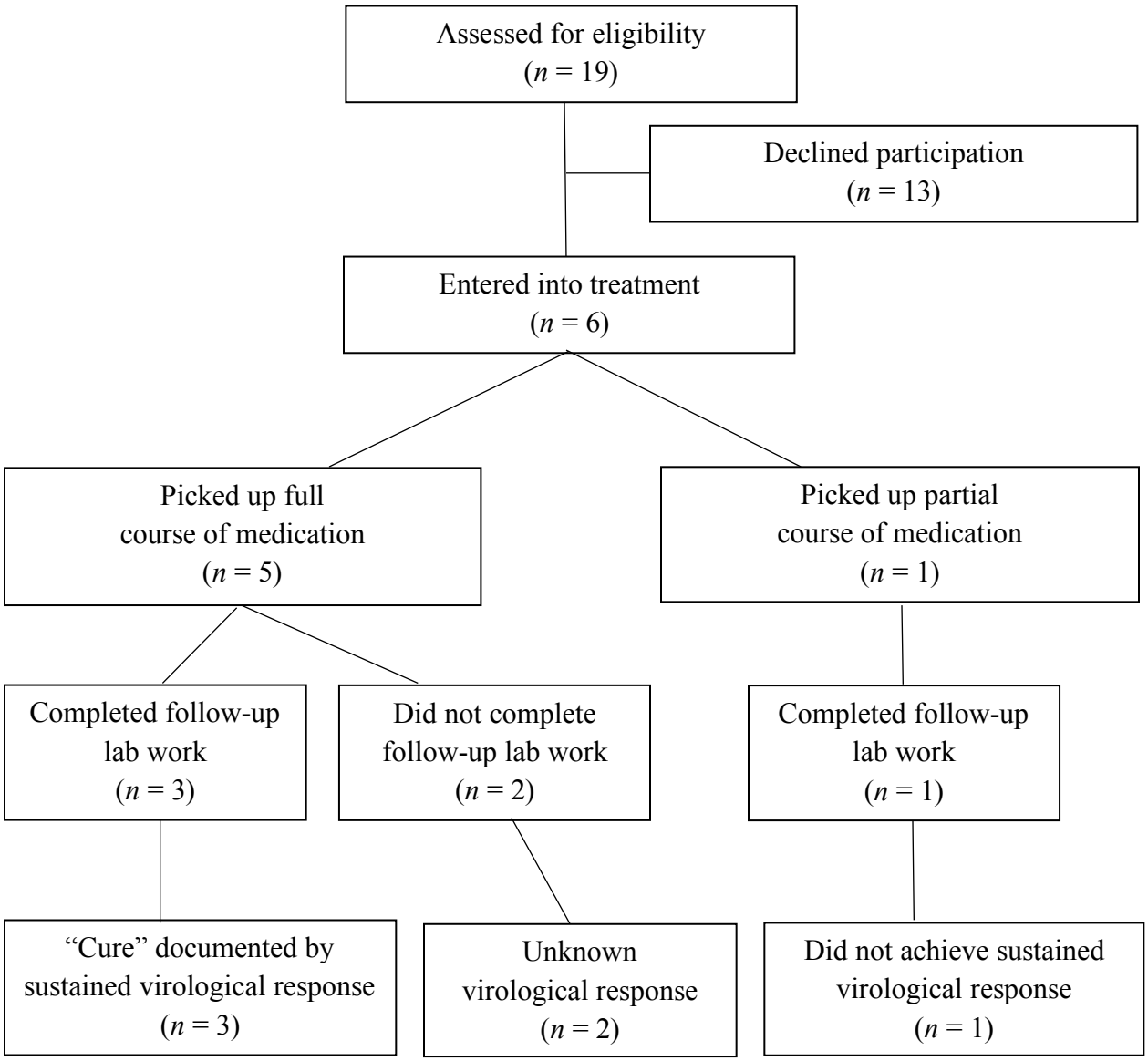
At the outset of this project there were 19 people identified as patients of the Alamo Clinic who had detectable Hepatitis C viral loads. All 19 patients were aware of their disease status and all were contacted by the CHR or BHL and offered treatment. Thirteen declined to enter the HCV treatment protocol for undisclosed reasons.

During the project period, six patients (31.6%) chose to receive treatment for HCV at the Alamo Clinic. Three of these patients (50%) were presented by the medical director at the Alamo Clinic to Project ECHO for tele-mentoring. The remaining three patients (50%) had no comorbid conditions, and the medical director determined that he was able to follow the Project ECHO treatment algorithms without presenting the patient at a tele-conference.

See Figure 2 for the flowchart of patient decisions and responses during the project.

Figure 2

Flowchart of Patient Decisions and Responses to Phases of Treatment.



All six of the patients who consented to treatment were successfully contacted by the CHR or BHL for follow-up care on multiple occasions. Both the CHR and BHL had permission to drive patients to the clinic for lab work, appointments or medication pick-up. Of note, five of six patients (83.3%) did pick up all prescribed medication and therefore these five patients completed the full

course of drug therapy according to the local pharmacist (T. Zemenfes, personal communication, July 2019). One patient completed a partial course of drug therapy. Obtaining follow-up lab work was the most challenging aspect of this project. The CHR provided in-person reminders at least once to all patients who had lab work due. Four of the six patients (67% of the participants) returned for lab work at or after 12 weeks post-treatment and three (50% of the participants) achieved SVR.

For the three patients whose cases were presented to Project ECHO by the clinic medical director, two achieved SVR following a full course of drug therapy. The third patient presented to ECHO was determined to be a treatment failure. This patient did not complete a full course of drug therapy and declined further care. Options presented to the patient included referral to a specialist, or having their case presented to Project ECHO again for follow-up and advice on how to proceed with care through the Alamo clinic. All three of the patients whose cases were not presented by the medical director completed their full course of medication. One achieved documented SVR. The other two did not complete their lab work and so their virologic response to the full course of medication was unknown.

Discussion

Of the 19 positive cases of HCV at the start of this project, we observed completion of treatment for five patients (26.3%) and confirmed "cure" of HCV for three patients (15.8%). While there is clearly a continued need for HCV treatment at this clinic, these results were an improvement over having only one patient treated in the years prior to implementing this quality improvement project. Of importance in monitoring the success of future implementation of HCV care in a rural clinic setting, the six patients who entered treatment were motivated to complete drug treatment but not necessarily to complete laboratory testing. This is evidenced by five of six

patients picking up their medication, but only four patients completing follow-up laboratory testing. To compare these results to those of other facilities, a *Morbidity and Mortality Weekly Report* stated that approximately 46% of all patients seen by a Project ECHO connected provider actually started HCV treatment. In comparison, 14-22% of patients receive treatment for HCV in the absence of Project ECHO's availability (Mitruka et al., 2014). While the treatment rate for this facility was lower than 46%, this may potentially be attributed to a small sample size or to a particular level of privacy and stigma in this community where patients personally know many staff members in the clinic and are hesitant to present for HCV care.

Lippitt's Phases of Change Theory was a useful framework to guide this project. Having a change agent (Project Manager) dedicated to developing the workflow and identifying the roles of the support staff was crucial to navigating the challenges that arose in terms of patient contact and follow-up. The Alamo Clinic faces a constantly changing medical staff, a very busy medical director, and an enthusiastic CHR and BHL who are consistent members of the team. Having defined roles and a project plan to follow supported the Alamo Clinic staff in implementing HCV treatment, with Project ECHO as a support for the medical director. Although some of the patients in this project entered HCV treatment at their own request, some entered after being contacted by the CHR or BHL. Following entry into treatment, the CHR and BHL contacted people in person or by phone and were able to locate and communicate with patients readily. Patients were willing to come in to have visits regarding initiation of treatment and to pick up medications. The availability of the CHR and BHL with vehicles to visit patients at home, and offer transportation to the clinic, was a valuable resource that may not be available in all rural clinics.

As far as staff time and effort, it was found that it is important to have a champion and "go-to" person who acted as the change agent and followed Lippitt's Phases of Change Theory. HCV

care has not been provided in the primary care setting until very recently, and as such it is intimidating to many at all professional levels. Having one licensed person learn the lab requirements, become familiar with medication payment options, and establish a connection with Project ECHO was necessary to bring what used to be a specialty care service into the primary care setting. Additionally, patients expressed preference for having someone they knew they could contact, without divulging private details repeatedly, in order to obtain the information that they need.

While there were significant concerns at the outset of the project regarding costs of the medications, all patients were able to receive their medications paid for by Medicaid. In tribal clinics, patients may have Medicaid coverage if they are eligible, and receive care paid for by contract with the Indian Health Service (IHS) as a secondary payor. A tribal clinic receives funds from IHS but makes decisions on how to administer those funds at a local level. Notably, in all cases Medicaid reimbursed at a higher rate than the cost to the pharmacy of the medication. According to the local pharmacist (T. Zemenfes, personal communication, September 2019), the average wholesale price of the medication used to treat five of the six patients was $15,840 per month, but the actual cost billed to the Alamo Clinic was $4,215.25 per month. Medicaid reimbursement reflected the wholesale cost and was paid to Alamo Clinic as $14,002 per one-month supply per patient.

The bi-weekly conference with Project ECHO was underutilized during the project. More could have been learned about HCV care and associated issues by attending the bi-weekly tele-conference. This would be the role of a champion, to have someone learn and share information to elevate the quality of care provided throughout the clinic. The resources of Project ECHO, however, were essential for establishing HCV care at the Alamo clinic. Project ECHO provides a

wealth of free and up-to-date information on essential requirements for appropriate HCV care and medication selection. Additionally, the opportunity to present the very first patients who had ever agreed to be treated for HCV at this clinic provided needed support to the Alamo Clinic providers for expanding to this new domain of primary care services. Because the patients who agreed to receive treatment at the Alamo Clinic were predominantly healthy individuals without any complications of their HCV infections, the treatment guidelines available online were the most used resource and were rigorously followed in all six cases. Alamo Clinic provider and staff attendance at the Project ECHO tele-conferences would be essential if a patient developed complications related to their HCV progression or treatment.

Limitations

This facility has challenges and needs particular to the reality of having only one full time healthcare provider. Having the medical director serve as the HCV provider is not ideal, as this position requires many additional work responsibilities. It would be preferable for a provider to lead this type of project with dedicated time to regularly participate in Project ECHO sessions and manage patient care coordination concerns.

Lessons Learned

Treating HCV is possible in any rural clinic with the support of Project ECHO. All key information needed is readily available online and consults with a specialist are made accessible through tele-conference, as well as phone or email when appropriate. Additionally, connecting with others who are treating HCV in the primary care setting provided further support and resources to allow confidence in the clinical management. In retrospect, more time should have been devoted to attending the bi-weekly ECHO conferences as there are weekly didactic presentations and case presentations that could have added valuable information to the care

provided. This could be changed moving forward to provided dedicated time for a project champion to attend these conferences.

The challenges faced in this project were related to patient engagement and laboratory testing. Thirteen eligible patients did not participate in HCV treatment for unknown personal reasons. It is worth further exploring this issue as the treatment now is highly effective and readily available. It is not clear why some patients did not complete follow-up laboratory testing. Possibly more education was needed in this area either directly to the patients or delivered by the CHR and BHL.

Conclusions

Hepatitis C care has changed significantly with the availability of Direct Acting Antiviral medications and the support of telemedicine such as Project ECHO. Primary care providers are now able to diagnose and treat HCV if they are ready to obtain the modest amount of additional education necessary to do so. It is helpful to have clinic staff who are supportive of this treatment endeavor to effectively and efficiently coordinate care for these patients in a way that allows for the best outcomes in a respectful and private setting. Overall, Hepatitis C care through a rural clinic-Project ECHO partnership was found to be affordable, feasible and not excessively time consuming for a facility that has established patient outreach capabilities. The freely shared treatment guidelines from Project ECHO provide a reference that is always available, while the teleconferences enhance knowledge and provide the opportunity for consultation with a specialist when necessary.

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