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Strategies to Increase Primary Care Provider Capacity for Hepatitis C Care: The California ECHO-PLUS Study

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List of Abbreviations:

APPs: advanced practice provider HCV: hepatitis C virus IQR: Interquartile range PCPs: primary care providers

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Conflict of Interest:

The following authors report conflict of interest: Jeffrey McKinney Gilead Advisory Board Souvik Sarkar: Speaker: Eisai, institutional grant from Gilead Sciences Norah Terrault: Institutional grant from Gilead Sciences, Rebecca Hluhanich Gilead Sciences stock holder, institutional grant from Gilead Sciences

<u>Abstract</u>

Background: Expanding capacity to screen and treat those infected with the hepatitis C virus (HCV) is an essential element of the global elimination strategy. **Methods:** We evaluated the hub-and-spoke Project ECHO training versus telementoring models to educate, train and support HCV care by primary care providers in 13 targeted counties in northern California. A novel provider engagement strategy was used. Provider engagement and retention, time to readiness to treat HCV, and knowledge and confidence were the outcomes of interest.

Results: 94 participants from 60 unique clinics in the target counties participated in the ECHO-PLUS program; 39.4% were MD/DO, 48.9% advanced practice providers (APPs) and 11.7% nurses. The median (range) participation time was 5 (1-49) hours. Confidence scores increased by a mean of 14.0 (SD:8.2) and 11.4 (SD:12.0) points for the hub-and-spoke and telementoring programs, respectively (p=0.53), with the largest changes in confidence seen in treating patients per guidelines, managing side effects and in serving as a consultant for HCV in their clinic. Among 24 participants with data on time to treatment, median time from beginner to experienced was 8 hours (IQR:6-12) for hub-and-spoke and 2 hours (IQR:1-2.4) for the telementoring program (p=0.01).

Conclusion: A "boots on the ground" approach was effective in recruiting HCV champions within rural communities. Both tele-ECHO hub-and-spoke and telementoring approaches to training primary care providers yields increase in knowledge and confidence in HCV care and amplifies the number of patients who were screened and treated. Telementoring accelerates the timeline of novice providers being "ready to treat".

Introduction

California, as the most populous state in the United States, is estimated to have ~15% of all the Americans living with hepatitis C virus (HCV) infection¹. To meet the needs of these infected individuals, a broad base of HCV providers is necessary. As the diagnosis and treatment of chronic hepatitis C have become simpler and accessible to non-specialists, there has been great desire to shift the management of HCV to primary care providers (PCPs). Indeed, as PCPs are at the frontlines for screening for HCV, co-localizing treatment to those same providers is the optimal approach, reducing drop-off in the cascade of care related to referrals, access to care, and engagement by specialists. This is particularly important in non-urban areas, of which there are large areas in the state of California. Indeed, rural California accounts for 55% of the state's land mass though only 9% of the state's nearly 40 million population reside there. In these rural areas, the unequal distribution of health care providers, particularly specialists, presents a significant physical and financial barrier to receiving HCV treatment.

The best method to deliver education to PCPs to allow them to manage HCV care remains an important area of research. Project ECHO, developed in 2003, is a model of HCV training established to reach PCPs remotely, providing them education and support while they become local HCV champions. This hub-and-spoke educational model connects experts (hub) with non-specialists (spokes) virtually for didactic lectures and case-based learning and has been shown to be effective in supporting PCPs in managing HCV-infected patients^{2,3}. Telementoring is another model of HCV training that can be conducted virtually⁴. This model involves virtual, individualized one-to-one mentoring of non-specialists by specialists in the care of HCV-infected patients⁵. Both hub-and-spoke and one-on-one telementoring models have been used to meet the needs of rural counties but whether one method offers advantages over the other is unclear.

To address the clinical need for expansion of HCV care to rural Northern California, we developed ECHO-PLUS, a multi-faceted program to support PCP education in targeted counties with high prevalence of HCV. Within this program, providers were offered the opportunity to enroll in either (but not both) a hub-and-spoke program or one-on-one telementoring support. We evaluated the success of these programs in terms of provider engagement and outcomes in HCV care. We hypothesized that both methods would yield similar confidence and knowledge but that one-on-one telementoring would lead to faster readiness to treat.

Study Methods

This study was funded through a competitive RFP program funded by Gilead Sciences. The funders had no role in the design and implementation of the study, nor the data analysis or preparation of the manuscript for publication. The umbrella research program was called ECHO PLUS and included investigators from two academic institutions: The University of California San Francisco, which led the huband-spoke Project ECHO training model; and University of California Davis which led the Telementoring model. Both had previous experience facilitating their respective training approaches and established infrastructure in place to support rapid uptake of the endeavor ^{4,6}.

The target population for this education intervention was non-urban PCPs from 13 counties in predominantly northern California: Del Norte, Humboldt, Inyo, Lake, Lassen, Mendocino, Modoc, Plumas, Siskiyou, Shasta, Sutter, Trinity and Tuolumne (**Supplemental Figure 1**). These counties were selected for their high burden of HCV cases (based on 2015 data) and distance from specialist care. Primary care practices in each county were identified and PCPs contacted in person, by phone and email as to their interest in becoming an "HCV Champion" in their practice/community. At least one PCP was recruited per county with the proportion of PCPs participating in ECHO PLUS among total number of PCPs in the county varying from 1% to 51% (**Supplement Table 1**).

Recruitment Strategies: A traveling nurse educator/clinical outreach liaison was used to raise awareness within the local health jurisdictions and to do in-person recruitment to the ECHO-PLUS program. Using the provider databases provided by the Medi-Cal Managed Care organizations (Partnership and California Health and Wellness) a routing plan, much like a sales representative would use, was developed. Within these directories, primary care providers (internal medicine, family practice, and general practice) and their practice organizations were identified as potential participants. Once practices had been identified, the outreach nurse made preliminary phone calls to set appointments and where appointments were not offered, the nurse made cold calls once she arrived in the geography. Most often, getting an appointment with a provider required in person contact and relationship development with an influencer in the office setting. It is important to note that affiliation with large academic institutions (UCSF & UCD) as well as the nurse's credentials lent a credibility to the initiative. The outreach nurse wore a nametag with her credentials and the ECHO logo at all times when interacting with potential spokes.

Having a sense of data specific to the geography lent further credibility to the outreach nurse's presence and allowed for talking points that were very specific to the geography. Resources, such as the County Health Rankings (<u>https://www.countyhealthrankings.org</u>), were used. This resource provided the county's health ranking within the state, ratio of PCPs to residents, and other social and economic factors that contribute to health outcomes. Other strategies to engage clinicians included connecting with the local medical society and running an ad in their quarterly publication, meeting with the coroner to learn about overdose related deaths and their relationship to IV drug use, relationship development with public health officers and clinicians, connecting with tribal health representatives on a national level and providers at a local level, and partnering with harm reduction/syringe exchange facilities. Outreach was also aimed at the people in the community through participation in local health fairs, radio and TV appearances, newspaper articles about the ECHO Plus program as it related to HCV in the local community. The strategy was to saturate the community, at all levels, with as much information as possible about HCV. Soft goals included increase in awareness about HCV and de-stigmatization.

Interventions: PCPs were described the two modes of training in detail and invited to enroll in one program exclusively. The time commitment and expected level of

participation was presented and PCPs were asked to select the program that best suited their needs. The time and number of sessions that each training program recommended were specified.

In brief:

- For Hub-and-Spoke model (Project ECHO format). PCPs were asked to attend biweekly 1-hour sessions, held at lunch time to facilitate participation. Each session consisted of a 20-minute didactic on an HCV-specific topic followed by case presentations and case-based learning. PCPs were expected to participate in at least 10 sessions before being considered ready to start treatment independently. However, there was an option for participation in a 4-hour "immersion" event that condensed the educational elements into a single day, such that readiness for treatment could occur before more rapidly. Ongoing participation was encouraged even after the minimum 10hour equivalent of attendance was attained. For "between hub-and-spoke sessions" questions, participants were provided with a 1-800 "warm line" for support staffed by provided at the Hub.
- 2) For telementoring, participants. In this model, PCPs ('mentee') attended an introductory didactic session on the principles of HCV diagnosis and treatment. After this introductory session, a one-to-one telemedicine-based consultation along with the patient (at the PCP's office), with the 'mentor' site was scheduled. The mentor site comprised of HCV specialists (hepatologists or internist specialized in treating HCV patients) and HCV specialty pharmacist. At least 10-hours of mentoring was recommended but the total number of hours could be lower depending on mentee and mentor determination of 'readiness-to-treat. After 10 hours of participation in their selected program or after obtaining 'readiness-to-treat', participants from the telementoring program could cross-over to the Project Echo if desired. For "in-between telementoring session" questions, participants were provided with the contact number of the mentor team providing the telementoring session.

PCPs did not receive financial support to participate, though the Project ECHO huband-spoke and the telementoring program offered CME credit for the didactic components of the program. Measures and Outcomes: Upon agreement to participate in either program, a pre-test was done. This pre-test was a self-assessment of confidence (using a 5point Likert scale) in performing screening, assessing liver disease severity, identifying suitable candidates for treatment, treatment per guidelines and managing side effects. They were also asked about confidence in treating more complex patients, such as those with human immunodeficiency disease or substance use disorders or cirrhosis. These same assessments were repeated after participants had completed at least 10 hours of participation or were deemed 'ready-to-treat'. Participation in pre and post-tests was voluntary, though we did use a modest incentive (lottery style) to encourage post-test completion when it was recognized that response rates were low. At the end of the ECHO-PLUS grant, all participants were asked to complete an outbound survey indicating the frequency of screening and treatment of hepatitis in their practice. Provider characteristics measured included location, whether MD/DO or Advanced Practice Provider (APP) and if prior HCV treatment experience (defined as having treated HCV patients in the prior 12-months for the hub-and-spoke group or specifically with peginterferon+ribavirin in the telemedicine group).

Statistical Analysis:

The statistical analysis included three components: (1) the participation assessment including all study participants, (2) the pre- and post-training assessment including only MD/DO and advanced practice providers completing both the pre-test and post-test assessments (nurses excluded), and (3) the outbound assessment including all study participants completing the outbound survey. Cohort characteristics were described as frequencies with percentages for categorical variables and medians with interquartile ranges (IQR) for numeric variables. Comparisons by training program were assessed using chi-square, Fisher's exact, and Wilcoxon rank sum tests, as appropriate.

For the pre- and post-training assessment, radar plots were created to visually depict the median pre- and post-test scores for each domain. The change in knowledge and confidence scores was then calculated as the difference between pre- and post-training assessments with positive values indicating scores increasing from baseline and negative values indicating scores decreasing from baseline. Score changes were summarized as means with standard deviations (SD) and were compared by training program using the t-test.

Results:

Study Participants:

From 10/2017 through 6/2020, 94 participants from 60 unique clinics in the target counties accepted the invitation to participate in the ECHO-PLUS program. Among participants, 37 (39.4%) were MD/DO, 46 (48.9%) were APPs and 11 (11.7%) were nurses.

Engagement

Of those PCPs agreeing to participate, 79 opted for the hub-and-spoke training (Project ECHO) and 15 opted for 1-1 telementoring **(Table 1).** The proportion of the hub-and-spoke versus telementoring programs that were MD/DO was 40.5% vs 33.3%, APPs was 45.6% versus 66.7%, and nurses was 13.9% versus 0.0% (p=0.22). Of the 79 participating in the hub-and-spoke training, the majority (86.1%) completed the 4-hour HCV "immersion" as part of their training.

Retention was measured by number of hours of attendance in training opportunities. Amongst the 94 participants, the median (IQR) length of participation was 5 (3-9) hours with the range from 1 to 49 hours. The number of hours of participation were higher for PCPs in the hub-and-spoke training program (median 6, IQR 3-12) than 1-1 telementoring with median 1.5 (1.5-4 hours), p<0.001. 7.4% of PCPs were experienced (prior exposure to treatment during interferon era but lacked experience with direct-acting antivirals), 5.1% of the hub-and-spoke versus 20.0% of the telementoring training program (p=0.08).

Changes in Knowledge and Confidence of Participants

A total of 26 participants (73.1% from hub-and-spoke training; 26.9% from telemedicine training; 0.0% nurses) completed both the pre-test and post-test assessments. The median (IQR) hours of participation in the training program between pre and post-tests was 10.5 (5.5-14.0). All participants answered these questions on the pre and post-test. The median (IQR) confidence score pre-test was 29 (21-32) and post-test was 43 (36-50). There greatest areas of improvement are highlighted by the radar plots (**Figure 1A/B**), with increased confidence in all domains except for performing screening (already high at 4 of 5 at baseline) and treatment of patients with human immunodeficiency and if pregnant (low at baseline and remained low). The largest changes in confidence were seen in treating patients per guidelines, managing side effects and in serving a consultant for HCV in their clinic. The overall confidence score increased by a mean of 14.0 (SD 8.2) points for the hub-and-spoke training program and 11.4 (SD 12.0) points for the telementoring program (p=0.53) (**Table 2**).

Cascade of Care Outcomes Among Participants

A key outcome of the study was the time from start of training until ready to treat first patient and change in number of patients treated pre versus post ECHO-PLUS participation. Among 24 with data (N=18 hub-and-spoke, N=6 telementoring), median time from beginner to experienced was 7 hours (IQR 2-11), 8 hours (IQR 6-12) for hub-and-spoke and 2 hours (IQR 1-2.4) for the telementoring program (p=0.01). Among the 19 inexperienced providers, median time from beginner to experienced was 7.0 hours (IQR 2.4-11.0); 7.0 hours (IQR 6.0-12.0) for hub-andspoke and 2.4 hours (IQR 1.8-2.4) for the telementoring programs (p=0.02).

As part of the pre and post-test assessments, PCPs were asked how many patients have you treated in the past 12 months? For this analysis, nurses were excluded. Out of all 26 participants, 9 (34.6%) moved to a higher category and 12 (46.2%) remained the same for screening **(Figure 2A)**; 15 (57.7%) moved to a higher category and 8 (30.8%) remained the same for treating **(Figure 2B)**.

Outbound Survey

An end of study survey of screening and treatment activity (since 2015) was sent to all participants (nurses excluded), to gauge the potential impact of the training program on patient access to screening and treatment. A total of 20 of 83 (24.1% response among non-nurses), with no difference in response between training groups: 23.5% (16 of 68) among hub-and-spoke trainees versus 26.7% (4 of 15) of telementor trainees (p=0.75). Among those who reported screening patients, a median of 100 patients had been screened (IQR 38-200); median 124 screened (IQR 38-250) among hub-and-spoke trainees versus median 50 screened (IQR 30-125) for telementor trainees (p=0.32). Of those who reported screening, 75.0% reported treating; 81.2% of hub-and-spoke trainees and 50.0% of telementor trainees (p=0.25). The median number of patients treated per provider was 10 patients (IQR 3-20), with no difference in numbers treated per provider by the hub-and-spoke trainees (median 10, IQR 3-20) versus the telementor trainees (median of 7, IQR 3-11), p=0.86.

Discussion:

The World Health Organization has set the ambitious goal of achieving HCV elimination by 2030. The United States is not on track to meet this target and there has been a call for renewed efforts to accelerate progress ⁷. A key element in achieving HCV elimination is to expand capacity to diagnose and treat the condition, and this is particularly true for rural America where specialist access is limited or non-existent⁸ and knowledge of HCV care among many primary care providers is low ⁹.

The Project ECHO model, described as a hub-and-spoke model of building primary care clinicians' capacity to treat chronic diseases, is well-recognized ^{2,10,11}. Uniquely, our study explored two different programs of educating and building capacity among primary care. We took advantage of another well-established model of primary care education –telementoring ¹². We hypothesized that one-on-one mentoring coupled with seeing a patient concurrently might be a desirable strategy to build HCV management skills. This was relevant since previously cited barriers to Project ECHO participation include lack of time to participate and the absence of reimbursement for participation. The telementoring model overcomes some of

these limitations. Interestingly, we found that the Project ECHO model was more frequently utilized than the telementoring model. As the Project ECHO program offered an intensive 4-hour immersion option, it is possible that those eager to get up to speed quickly favored this option. In fact, the immersion experience was highly subscribed to and may be an important means of engagement and capacitybuilding.

A key outcome of our study was the time to treatment readiness, and we found that this was achieved with significantly fewer hours of training with the telementoring model compared to the hub-and-spoke model. The one-on-one telementoring may lead to higher levels of active engagement thereby leading to accelerated learning and confidence. In the hub-and-spoke model, participants can take a more passive role in learning (listening rather than presenting cases) and are potentially less able to shape the learning session to meet their knowledge needs. Regardless, both methods of education yielded providers with confidence and knowledge to undertake treatment with a modest investment of time, on average 1.5 hours for telementoring and 6 hours for hub-and-spoke training. This suggests a role for both types of education with the trade-offs for the training program being quantity versus speed.

Ultimately, the outcome of capacity-building endeavors that is most relevant is the increase in numbers of HCV-infected persons screened, diagnosed and treated. In a recent cohort analysis of Medicare beneficiaries who sought care from 2006 to 2017 with follow-up to 2020 and evaluated the association of receipt of DAA therapy with presence of Project ECHO in the state. The analysis included 243,160 patients in states that had launched Project ECHO between 2006 and 2017 and 24,748 patients in states that had never implemented Project ECHO. Compared with states that never implemented Project ECHO, those states that implemented Project ECHO, the odds of initiating a DAA among patients with HCV infection increased by 9% (adjusted odds ratio 1.09; 95%CI, 1.07-1.11; P<.001) for each additional 100 clinicians attending the program. Our Project ECHO program launched during this time and California was one of the states included in the "with Project" group. While we did not track numbers of patients treated prospectively in our study, our outbound survey indicated that three-quarters of participating providers were

prescribing DAA therapy and had treated 10 patients on average during the study period, yielding a total of \sim 630 patients treated.

A challenge faced by the tele-ECHO training model is the lack of resources to support participants and trainers. PCPs cite lack of time as a major hurdle^{13,14}. We scheduled our biweekly Project ECHO clinic to the noon hour to facilitate primary care providers being able to incorporate learning in their busy schedules. Provision of CME credit for the didactic sessions was another means of adding value to the time spent in the virtual ECHO clinics. Ultimately reimbursement for provider time (both educator and trainee) is needed. Various State Medicaid Financing Models for Project ECHO have been proposed (<u>https://www.chcs.org/media/ECHO-Financing-Matrix_120117.pdf</u>). In the Project ECHO in West Virginia, the state's Medicaid program accepted case presentations made during the Hepatitis C ECHO session as the specialty consultation requirement (e.g., hepatologist or infectious diseases) for Medicaid coverage of hepatitis C drugs, thus simplifying the care of patients within the practice and providing a tangible benefit to both primary care and specialty practices.¹⁵

An important component of our ECHO-Plus study was recruitment of PCPs. The outreach efforts required to convince a busy PCP of the value of becoming an HCV "champion" within their practice should not be underestimated. Indeed, most publications on Project ECHO fail to delineate the strategies for this initial engagement. In our study, we had a nurse recruiter, who lived within each county for months at a time, and during this time met with community leaders, local departments of health and primary care providers for the sole purpose of raising awareness of the importance of HCV in their community and to seek out those providers with interest in gaining expertise in managing the condition. The utility of having a "boots on the ground" approach was innovative and proved effective. Presence in each county for an extended periods of time allowed for relationship building, and the creation of solutions using available local resources. The outreach required to engage primary care providers likely differs across clinical settings, but we believe that community saturation with HCV messaging that is "regionally specific" is an important step in engaging primary care providers in rural communities.

Our study has some limitations. As all the PCPs were volunteers in this study, there was no requirement for participants to complete the surveys. This contributed to the missingness in the pre-post knowledge tests and determination of our primary outcome – readiness to treat. We acknowledge that respondents are likely to be different from non-respondents and thus represent the most "optimistic" view of our outcomes. Nonetheless, having responses from participants in both types of learning programs allow us to compare the two different programs. Additionally, there is not equal representation of PCPs across counties, with one county (Humboldt) contributing half the study participants and thus potentially introducing a potential center bias. Nonetheless, our study represents one of the few to compare different models of capacity-building and sheds light on the strengths and weakness when applied in rural settings.

In summary, building capacity for HCV care among PCPs in Northern California was successfully achieved using Project ECHO hub-and-spoke and telementoring strategies, with both training methods yielding increases in knowledge and confidence in HCV care and amplifying the number of patients who were screened and treated. This work highlights the benefits of different technology-supported platforms to support primary care-specialist partnerships to positively enhance patient care in non-urban areas.

Figure 1: Comparison of confidence scores among ECHO-Plus participants.

The pre-participation scores are shown in yellow and post-participation (at least 10 hours of training) in purple (N=26). Figure 1A focuses on screening and diagnosis questions and Figure 1B on treatment-related questions. Increased confidence was seen in all domains except for performing screening (already high at 4 of 5 at baseline) and treatment of patients with human immunodeficiency and if pregnant (low at baseline and remained low).

Participants Characteristics	Hub-and-Spoke Training (N=79)	Telemedicine Training (N15)
MD/DO, n (%)	32 (40.5)	5 (33.3)
APPs, n (%)	36 (45.6)	10 (66.7)
Nurses, n (%)	11 (13.9)	0 (0.0)
Experienced, n (%)	4 (5.1)	3 (20.0)
Attended HCV immersion, n (%)	68 (86.1)	NA
Hours of participation, median (IQR)	6 (3-12)	1.5 (1.5-4)
Completed pre- and post- confidence surveys, n (%)	19 (27.9)	7 (46.7)
Time to treat, median (IQR)*	8 (6-12)	2.1 (1-2.4)

Table 1: Participant Characteristics by Type of Training Opportunity

IQR: interquartile range. APP: advanced practice provider. NA = not applicable

* Only available for N=24 (18 hub-and-spoke, 9 telemedicine training)

 Table 2: Ranked Mean Changes in Confidence by Type of Training Program

Overall (N=26)		Hub-and-Spoke Training (N=19)		Telemedicine Training (N=7)	
Domain	∆ Scor e	Domain	∆ Scor e	Domain	∆ Scor e
Treat patients with HCV according to AASLD-IDSA guidelines	+1.8	Treat patients with HCV according to AASLD-IDSA guidelines	+1.9	Treat patients with HCV according to AASLD-IDSA guidelines	+1.6
Manage the side effects of HCV treatment	+1.2	Identify suitable candidates for treatment for HCV	+1.4	Manage the side effects of HCV treatment	+1.6
Provide consultation to other primary care providers to care for patients with HCV	+1.2	Provide consultation to other primary care providers to care for patients with HCV	+1.3	Educate and motivate patients with HCV	+1.4
Identify suitable candidates for treatment for HCV	+1.1	Manage HCV treatment of patients with cirrhosis	+1.2	Provide consultation to other primary care providers to care for patients with HCV	+1.0
Educate and motivate patients with HCV	+1.0	Manage the side effects of HCV treatment	+1.0	Manage HCV treatment of patients with end stage renal disease	+0.9
Manage HCV treatment of patients with cirrhosis	+1.0	Identify patients who should be screened for HCV	+0.8	Assess severity of liver disease in patients with HCV	+0.7
Identify patients who should be screened for HCV	+0.8	Educate and motivate patients with HCV	+0.8	Identify patients who should be screened for HCV	+0.7
Manage substance abuse comorbidities in patients with HCV	+0.7	Manage substance abuse comorbidities in patients with HCV	+0.7	Manage substance abuse comorbidities in patients with HCV	+0.6
Assess severity of liver disease in patients with HCV	+0.6	Perform screening tests for HCV	+0.6	Identify suitable candidates for treatment for HCV	+0.4
Manage HCV treatment of patients with end stage renal disease	+0.6	Assess severity of liver disease in patients with HCV	+0.6	Manage treatment in persons with HIV	+0.4
Perform screening tests for HCV	+0.5	Manage HCV during pregnancy	+0.5	Manage HCV treatment of	+0.4

				patients with cirrhosis	
Manage HCV during pregnancy	+0.4	Manage HCV treatment of patients with end stage renal disease	+0.5	Perform screening tests for HCV	+0.1
Manage treatment in persons with HIV	+0.3	Manage treatment in persons with HIV	+0.3	Manage HCV during pregnancy	+0.1
Overall ∆ Confidence Score	+13. 4		+14. 0		+11. 4

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