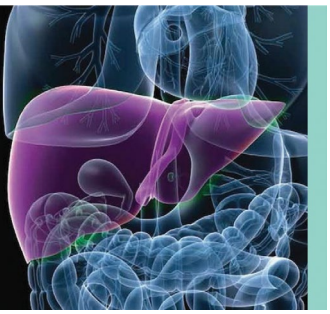

HCV Elimination in the US Department of Veterans Affairs

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Since 2014, the US Department of Veterans Affairs (VA), the largest single provider of care for chronic hepatitis C virus infection (HCV) in the United States, has virtually eliminated HCV among Veterans in VA care (Fig. 1). The VA's experience provides lessons learned to other healthcare organizations (HCOs) pursuing HCV elimination.

The discovery two decades ago that HCV is three times more prevalent among Veterans in VA care than in the general US population[1,2] prompted the VA to launch a comprehensive national HCV program focused on provider and patient education, quality improvement, data dissemination, and clinical tool deployment (Table 1).

Abbreviations: CCR, clinical case registry; DAA, direct-acting antiviral agent; ERIC, Expert Recommendations for Implementing Change; HCO, healthcare organization; HCV, hepatitis C virus; HIT, Hepatitis C Innovation Team; LT, leadership team; SME, subject matter expert; SVR, sustained viral response; VA, US Department of Veterans Affairs; VAMC, VA Medical Center; VISN, Veterans Integrated Service Network.

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For more information, please visit: Hepatitis C Overview - Viral Hepatitis and Liver Disease (va.gov).

SR's time was funded by NIDA K23 DA048182 and this work was partially funded by QUERI PEC 19-307 and HHRC.

Potential conflict of interest: Timothy Morgan participated in hepatitis C clinical trials funded by AbbVie, Gilead, Merck, and Hoffman-LaRoche.

Received June 22, 2021; accepted June 25, 2021.

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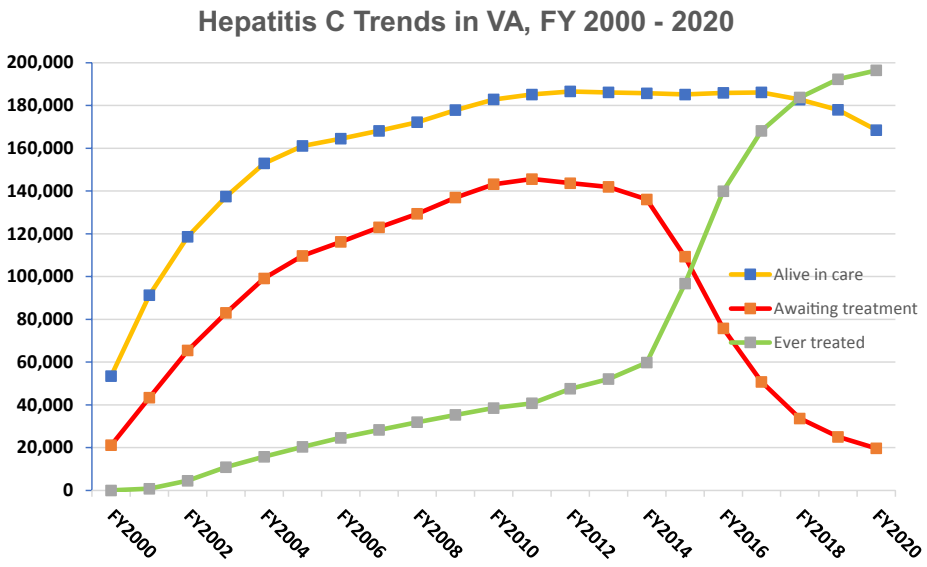

FIG 1 Number of Veterans in care at VA facilities (yellow line), the number of Veterans awaiting HCV treatment (red line), and the number of Veterans ever treated for hepatitis C (green line), between fiscal year FY 2000 and FY 2020. Source: VA Hepatitis C Cube.

TABLE 1. COMPONENTS AND FUNCTIONS OF THE VA NATIONAL HEPATITIS C PROGRAM (HTTPS://WWW.HEPATITIS.VA.GOV/HCV/INDEX.ASP)

Component	Function
National HCV Program Office	National coordination and communication
HCV Clinical Case Registry (CCR)	Local and national capture of clinical, laboratory, and pharmacy data on all HCV+ Veterans in VA care[3]
Testing/treatment guidelines	Evidence-based standards for testing/treatment [4,5]
HCV Lead Clinicians	VAMC-level coordination and communication
Hepatitis C Resource Centers	Develop and disseminate innovations in HCV care[6,7]

The VA's national HCV treatment efforts were limited by the low efficacy and high toxicity of interferon-based HCV treatments, along with the high prevalence among Veterans in VA care with HCV.[7] Consequently, by 2014, fewer than 25% of approximately 170,000 Veterans with HCV in VA care had received treatment, with only 10% achieving a sustained viral response (SVR).

The VA's robust organizational HCV infrastructure – particularly the creation of a national HCV clinical case registry by the VA's Population Health office – prepared the VA to respond quickly when all-oral DAAs became available in 2014. Using this pre-existing foundation, the VA activated a unique network of VA Hepatitis C Innovation Teams (HITs) – small, agile, field-based units focused on rapid clinical system redesign and innovation to improve HCV care. The HIT concept followed Berwick's framework for innovation dissemination in healthcare, which posits the importance of first identifying strong evidence-based practices and innovators, investing in and learning from early adopters, supporting change, and leading by example (Table 2).[8]

HITs were established within each Veterans Integrated Service Network (VISN; a geographic region containing multiple VAMCs). Each HIT was composed of subject matter experts (SMEs) in HCV, clinical pharmacy, system redesign, and informatics. Each VISN HIT was funded by the national HCV program but focused on issues specific to that VISN. As described below, the HITs had the same quantitative access and quality goals but were autonomous in choosing the route and projects for achieving these targets.

We surveyed VA HCV clinicians and HIT participants about 73 implementation strategies or activities used at their facility. Implementation strategy definitions followed the Expert Recommendations to Implement Change (ERIC).[9] Each strategy was evaluated for the strength of its association with the number of DAA treatment starts at each facility from 2015 to 2019.[10-12] Eight implementation strategies, clustered thematically into three groups, were consistently associated with higher annual DAA treatment starts. These strategies, described below, provide an

HCV-elimination roadmap for public health agencies and other HCOs (Table 2).

SUCCESSFUL IMPLEMENTATION STRATEGIES

Thematic Cluster 1: Develop and Lead a Provider Network

Strategy 1: Facilitate the Formation of Groups of Providers and Foster a Collaborative Learning Environment. A national leadership team (LT) that included VA leadership, a hepatologist, and personnel trained in public health, informatics, and systems redesign oversaw the VISN HITs (Fig. 2). The LT supported HITs to identify barriers to HCV testing and treatment and to set ambitious annual goals for testing and treatment. The LT provided training and coaching to HITs on Lean process improvement, data management, and HCV clinical care/DAA use. The LT also sponsored work groups and established online and in-person opportunities for peer-to-peer networking and sharing ideas as well as facilitating communication with higher level policy makers. The LT prioritized a culture of safety and innovation, embracing failure as a precursor to change.

Strategies 2-4: Form Local Coalitions, Conduct Local Consensus Discussions, and Inform Local Opinion Leaders About Innovations in HCV Treatment. The LT facilitated the development of 20 VISN HITs, each with a designated leader and a multidisciplinary membership from the facility-based teams within the VISN. The HITs used Lean principles, derived from industrial engineering, to improve healthcare efficiency while maintaining the central importance of the patient.[13,14] VISN HITs retained autonomy to establish regional goals and prioritize innovations that met regional needs. HITs used A3 problem solving, tracked their progress, and shared their successes and challenges (Fig. 3). VISN teams worked closely with local facility and clinic leaders, facilitating consistent communication in a rapidly changing policy landscape.

Strategy 5. Identify Early Adopters and Learn From Their Experiences. The LT identified 'early adopters,' who successfully applied Lean to achieve innovations in HCV care and DAA treatment.[15] Early adopters presented

TABLE 2. THEORY OF DISSEMINATION OF HEALTHCARE INNOVATIONS ALIGNED WITH IMPLEMENTATION STRATEGIES AND EXAMPLES OF VA ACTIVITIES

Berwick Rule	Implementation Strategies That Were Successful in VA Efforts	Examples of Activities
Rule 1: Find Sound Innovations	Prior to DAA implementation HCRCs studied innovative treatment approaches *HCRCs studied innovative treatment approaches* *HCV Program Office developed data infrastructure* *HCV Program Office advocated for DAA availability*	Disseminate and promote adoption of HCV Treatment Considerations, standard guidance for testing and treating HCV
Rule 2: Find and Support Innovators	Develop learning collaborative (strategy 1) Identify and learn from early adopters (strategy 5) Build a local coalition (strategy 3)	Identify a leadership team Build the HIT as a learning collaborative with annual funding for each team
Rule 3: Invest in Early Adopters	Fund and support a national learning collaborative (including support for local HIT leader salary and innovative projects) (strategies 1-4)	Mobile clinics to reach underserved populations
	Purchase equipment (strategy 8)	Purchase a FibroScan to improve pre-treatment assessment
	Change the location of HCV care (strategy 7)	Community-based provision (outside the medical center) of HCV screening and treatment Open new clinics to meet local demand Redesign clinic space to accommodate group medical appointments or non-traditional provider clinics
Rule 4: Make Early Adopter Activity Observable	Learn from early adopters (strategy 5)	HITs shared their progress on innovations on monthly, virtual meetings
	Use data experts to highlight high performing VAMCs (strategy 6) Conduct local consensus discussions and inform local opinion leaders about advances in HCV care (strategies 4-5)	Data on progress towards annual goals was shared across HITs
Rule 5: Trust and Enable Reinvention	Foster a collaborative learning environment (strategy 1)	Use of Lean enabled teams to test change and use A3 problem-solving
Rule 6: Create Slack for Change	Adapt infrastructure-Rapid tests of changes (part of systems redesign) (strategies 6-8)	Early use and demonstration of data tools evolved into development and widespread adoption of the National HCV Dashboard
Rule 7: Lead by Example	Include stakeholders in the leadership team (strategy 1)	HCV Lead Clinicians were included on HITs

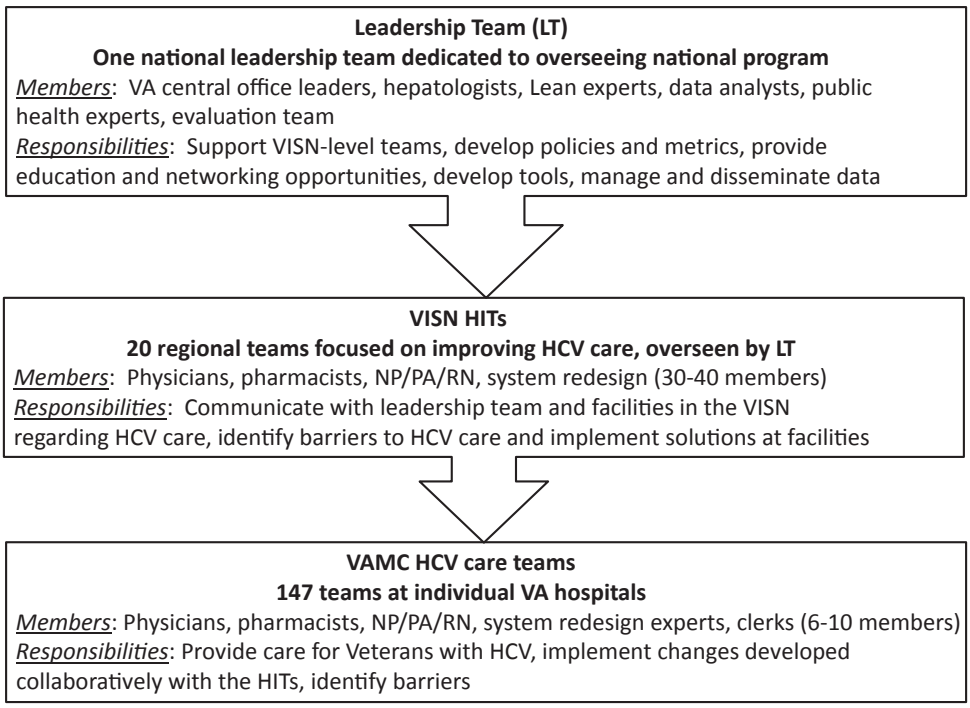

FIG 2 Organizational structure of the hepatitis c innovation team (HIT) learning collaborative.

to their peers during national and regional team calls. A virtual platform allowed teams to share their experiences with members who could not attend structured meetings.

Thematic Cluster 2: Use a Data-Driven, Population Health Approach to Care

Strategy 6: Use Data Experts to Develop and Disseminate Dashboards For Population Health-Based Care. The VA's preexisting clinical case registry (CCR) had data on all Veterans in VA care known to have HCV, with individual facilities having local CCRs.[3] However, DAA availability created a pressing need for user-friendly and locally available methods to identify and link Veterans with HCV to care. To improve access to this information, several VISN HITs independently developed user-friendly HCV Dashboards, which were coalesced to create a national Dashboard. These data were then used by providers at each facility to identify untreated patients and by the LT to monitor progress across the VA, creating positive competition for quality improvement. A suite of tools was created to document HCV screening, evaluation, and treatment decisions. Tools also included triggers within the electronic medical record to prompt re-evaluation of Veterans who had previously deferred HCV treatment. This platform allowed the LT to collect data from users that could inform policy. Because the HCV Dashboard was built to meet the needs of stakeholders, it was widely accepted by the HITs and was critical in the paradigm shift from referral-based HCV treatment to non-specialist care by primary care physicians and clinical pharmacists.

Thematic Cluster 3: Change Infrastructure to Facilitate Rapid Treatment

Strategy 7: Change the Location of HCV Care. The most successful HITs changed the way HCV care was delivered by engaging non-traditional providers in treating HCV. Pharmacist-led clinics, group visits, and primary care treatment were all used to expand capacity and treat outside of the traditional hepatology and infectious diseases settings. Approximately 30% of DAA treatment was managed by clinical pharmacists, with SVR rates similar to Veterans receiving treatment by specialists.

Strategy 8: Purchase (and Increase Access to) Equipment. VA recognized the need to assess patients for cirrhosis and to evaluate patients with cirrhosis for liver cancer prior to initiating HCV treatment. As such, improving access to ultrasound examination and vibration-

Title	Team: Owner:	Start Date:	Date Last Updated:
1. Reasons for Action (performance gap, problem statement)	**4. Gaps Analysis** (gaps/barriers between current & future states)	**7. Completion Plans** (implementation/sustainment plans – "Act")	
2. Current State (description, charts, pictures)	**5. Solution Approaches** (Countermeasures, in form: If…, Then…)	**8. Confirmed State** (Results)	
3. Target State (may include ideal state or a couple time horizons)	**6. Rapid Experiments** (first cycle PDSAs)	**9. Insights** (Lessons Learned)	

FIG 3 A3 Problem-solving template, used by HITs to document process improvement innovations.

controlled transient elastography to assess liver fibrosis was critical to screen and risk-stratify patients prior to treatment initiation. Therefore, funds were provided to purchase elastography and other equipment. The HIT infrastructure also supported a working group of providers to develop and disseminate tools and training about transient elastography methods and equipment.

DISCUSSION

Two decades of leadership by dedicated VA clinicians supported by the VA National HCV Program Office provided the infrastructure for rapid expansion of HCV care following the availability of DAAs in 2014. These efforts included testing Veterans in VA care for HCV, identifying HCV lead clinicians, and using a population health management tool. The HITs used Lean approaches to identify and overcome local barriers to care. The implementation strategies empirically associated with higher treatment were also those that aligned with the Theory of Dissemination of healthcare innovations.[8] As a learning healthcare system, the VA is now applying these lessons and approaches to improve care in the areas of HIV prevention and care and cirrhosis care. This work can serve as an example for other healthcare organizations aiming to eliminate HCV.

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REFERENCES

1) Dominitz JA, Boyko EJ, Koepsell TD, et al. Elevated prevalence of hepatitis C infection in users of United States veterans medical centers. Hepatology 2005;41:88-96.

2) Roselle GA, Danko LH, Mendenhall CL. A four-year review of patients with hepatitis C antibody in Department of Veterans Affairs facilities. Mil Med 1997;162:711-714.

3) Backus LI, Gavrilov S, Loomis TP, et al. Clinical Case Registries: simultaneous local and national disease registries for population quality management. J Am Med Inform Assoc 2009;16: 775-783.

4) Yee HS, Chang MF, Pocha C, et al. Update on the management and treatment of hepatitis C virus infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. Am J Gastroenterol 2012;107:669-689. quiz 690.

5) Department of Veterans Affairs Hepatitis CRC, Yee HS, Currie SL, Darling JM, Wright TL. Management and treatment of hepatitis C viral infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center program and the National Hepatitis C Program office. Am J Gastroenterol 2006;101:2360-2378.

6) Knott A, Dieperink E, Willenbring ML, et al. Integrated psychiatric/medical care in a chronic hepatitis C clinic: effect on antiviral treatment evaluation and outcomes. Am J Gastroenterol 2006;101:2254-2262.

7) Mendenhall CL, Moritz T, Rouster S, et al. Epidemiology of hepatitis C among veterans with alcoholic liver disease. The VA Cooperative Study Group 275. Am J Gastroenterol 1993;88:1022-1026.

8) Berwick DM. Disseminating innovations in health care. JAMA 2003;289:1969-1975.

9) Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci 2015;10.

10) Rogal SS, Yakovchenko V, Waltz TJ, et al. Longitudinal assessment of the association between implementation strategy use and the uptake of hepatitis C treatment: Year 2. Implement Sci 2019;14:36.

11) Rogal SS, Yakovchenko V, Waltz TJ, et al. The association between implementation strategy use and the uptake of hepatitis C treatment in a national sample. Implement Sci 2017;12:60.

12) Yakovchenko V, Miech EJ, Chinman MJ, et al. Strategy Configurations Directly Linked to Higher Hepatitis C Virus Treatment Starts: An Applied Use of Configurational Comparative Methods. Med Care 2020;58:e31-e38.

13) de Koning H, Verver JP, van den Heuvel J, Bisgaard S, Does RJ. Lean six sigma in healthcare. J Healthc Qual 2006;28:4-11.

14) Park A, Gonzalez R, Chartier M, et al. Screening and treating hepatitis C in the VA: achieving excellence using lean and system redesign. Fed Pract 2018;35:24-29.

15) Dearing JW, Cox JG. Diffusion of innovations theory, principles, And Practice. Health Aff (Millwood) 2018;37:183-190.