CONSULTATION REPORT

Expert Consultation on the Evidence for Early Hepatitis C Treatment in the United States

Department of Health and Human Services

Office of the Assistant Secretary for Health
Office of HIV/AIDS and Infectious Disease Policy

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Key Issues & Actions

Consultation Overview

The Office of Assistant Secretary for Health convened a consultation on September 12-13, 2016 to 1) review the best available evidence regarding the costs and economic benefits of early hepatitis C virus (HCV) treatment; 2) identify barriers to accessing HCV treatment with direct-acting antiviral agents (DAAs) as well as gaps in economic and scientific data and policies; 3) highlight health care delivery models that have been effective in expanding access to HCV treatment; and 4) identify potential strategies for strengthening the business case for and expanding HCV treatment. The complete meeting agenda is included in Appendix A.

The summary below captures key issues in understanding and addressing the benefits of HCV treatment and describes potential actions in the following areas: payer restrictions, DAA cost and price, improving HCV surveillance and health care data, HCV treatment outcomes, health care system capacity, and HCV screening. These topic areas were identified by participants to be important to payers, health systems, providers, patients, and advocates working to ensure that the United States realizes the full potential benefits of the newly available, highly effective curative treatment for the estimated 3.5 million people living with chronic HCV.

Participants

A total of 34 stakeholders participated in the consultation, including public and private payers, healthcare providers, academic researchers, representatives of professional associations, hepatitis advocates, and federal partners. A full participant list is included in Appendix B.

Understanding and Addressing the Benefits of HCV Treatment

- The available DAAs for treatment of chronic HCV are highly effective in curing HCV and provide substantial health benefits to patients and society. At present, however, only a small proportion of Americans living with HCV have been treated.
- The perceived and actual costs of treatment are primary barriers to expanding access to HCV treatment.
- The Medicaid coverage landscape for DAAs differs widely by state and insurance plan, and continues to evolve rapidly. Legal challenges have led to a reduction in restrictions and improvements in access to DAAs in several states. Policies in place even several months ago may be very different today, and public misunderstanding of policies may prevent people from accessing HCV treatment.

- Categorical exclusions from, or exceptions to, expert clinical guidelines–which are considered the standard of care by healthcare providers–are not consistent with scientific evidence of the benefit of HCV treatment.
- Low rates of HCV screening and payer restrictions on what types of providers can prescribe treatment, the choice of treatment regimen, and patient eligibility characteristics (e.g., fibrosis score, substance use history) all limit access to HCV treatment.
- Policies related to screening practices, treatment selection, treatment authorization, treatment delivery, and data collection can impact the management of those with chronic HCV.
- Health care delivery models that increase the capacity to diagnose and treat HCV include (but are not limited to): teleconsultation, integrated and multidisciplinary team-based care, and the use of electronic health record (EHR) clinical reminders.
- Successful implementation of strategies to treat all those with HCV requires long-term plans for diagnosis and treatment of individuals over time. As such, forecasts and plans to address financial and capacity barriers should reflect a realistic, time-phased rollout of treatment rather than an expectation of the need to immediately treat the entire population of persons with HCV.
- Patients and patient advocates, providers, as well as pharmaceutical industry partners, should be engaged in activities targeting increased access to HCV diagnosis and treatment.

Key Issues & Potential Actions

Payer Restrictions

- Policies and restrictions regarding HCV treatment in state Medicaid programs, including Medicaid managed care organizations (MCOs), should be systematically assessed and monitored.
- Restrictions based on length of abstinence from alcohol and drug use are not evidence-based and should be removed. Strategies to improve outcomes for people with substance use disorders may include integrated care models, enhanced case management, and directly observed therapy.
- The policies, practices, and results of Medicaid programs (both fee-for-service [FFS] and MCOs) that have expanded access to early HCV treatment should be described and shared.
- Efforts should be made to describe and increase awareness of the strategies, benefit designs, and experience of private payers (such as Aetna and Kaiser Permanente) that promote screening and/or place no restrictions on HCV treatment.

- Prioritization of patients in urgent need of HCV treatment is one strategy that has been used to reduce the immediate cost and capacity concerns of payers and healthcare systems.
- States currently serve as "risk protectors" for public health insurance plans (via access restrictions, patient evaluation and provision of supportive services to improve outcomes, negotiating prices). Additional support in the form of legislation requiring federal involvement and funding that provides further "risk protection" is needed to support state Medicaid agencies in order to expand HCV treatment.
- HCV RNA testing after week 4 of treatment was a critical component of prior (interferon-containing) HCV treatment regimens as it was a strong predictor of treatment outcomes. This practice is less relevant for new DAAs; however, it remains a component of most HCV treatment guidelines. Some payers may use week 4 testing as an opportunity to evaluate medication adherence and discontinue treatment. Discontinuation of DAAs among patients with detectable HCV RNA at week 4 is not evidence-based and may lead to discontinuation of treatment in patients who would have achieved sustained viral response (SVR, also known as a virologic cure).

Direct-Acting Antiviral (DAA) Cost and Price

- The actual cost of DAAs to payers is not known and may vary widely. The current price of a course of HCV treatment may be $25,000 or less (vs. publicly reported prices that approach $100,000) depending on the regimen prescribed and the price negotiated by the health system, payer, or pharmacy.
- The creation of additional purchasing pools or groups of states, health systems, or programs (e.g., correctional health) that provide HCV treatment could support negotiation of lower drug prices.
- Identification of an acceptable "target price" for DAAs where most payers would agree that treatment benefits represent value to the health care system if all restriction were removed could support increased access.
- Analysis of Affordable Care Act (ACA)-related Medicaid expansion populations could be useful in developing estimates for HCV treatment costs among a relatively newly insured population.
- Costs above and beyond those of HCV drugs themselves should be included as part of the total cost calculations, including downstream cost savings.
- A detailed cost analysis stratified by patient eligibility parameters would provide granular data on the state-level HCV burden on Medicaid programs and illustrate true potential budgetary impact. Creation of a federal risk corridor based on the characteristics of the Medicaid-eligible population could help to identify additional persons who can be treated with minimal or no impact to the state budget.
- The potential value of increased price transparency was discussed. Mixed opinions were offered:

    - The lack of accurate data on prices paid (after discounts, rebates) was identified as a barrier to expanding treatment by payers, advocates, and researchers because the initial retail price was very high.
    - Concern was expressed that greater transparency would negatively affect the ability of some groups (e.g., pharmacies, health systems) to negotiate the best possible price.
- High out-of-pocket costs for patients are a barrier to HCV treatment. Strategies to address direct patient costs are needed.

Improving Data

- The expansion of national surveillance is needed to understand the true burden of disease and appropriately target efforts to screen and treat all people with chronic HCV.
- Existing large data sets (e.g., Centers for Medicare & Medicaid Services [CMS], commercial laboratories, Veterans Affairs [VA]) should be reviewed and analyzed for trends and up-to-date HCV cure cascades should be developed to support planning efforts.
- Several states (e.g., MA, NY, KY, TN) and cities (e.g., Philadelphia, San Francisco) have instituted mandatory reporting of all HCV tests–positive and negative results. This enables enhanced surveillance and analyses of disease burden. The quality and utility of this information should be evaluated before the practice is expanded to more areas.
- Data on HCV treatment outcomes is a high-priority need. One notable barrier to collecting expanded HCV data is the existing burden of mandated reporting that already strains the practice and data collection and analysis capacities of providers, health systems, and payers.
- The VA has extensive data on HCV screening treatment and outcomes of HCV treatment which could be used to inform public and private policy and practices for HCV care nationally.

HCV Treatment Outcome Data

- Analyses of real-world treatment utilization, cure, resolution of extrahepatic complications, treatment failure, resistance, and reinfection rates, costs (including wraparound services), and short-term and long-term benefits would better inform cost models and assist with planning for expanding early HCV treatment.
- Stronger evidence-based guidance on selecting the shortest effective treatment duration (e.g., 12, 8, or fewer weeks) is needed. Providers without significant experience may lack confidence in selecting the most appropriate length of HCV treatment, thus increasing costs when longer than needed courses of treatment are chosen.
- Payers may be an important data source on rates of HCV treatment discontinuation, completion, and SVR.

- It is still relatively early in the DAA treatment evolution. As yet unknown side effects of treatment that become evident well after treatment discontinuation may emerge; thus the true lifetime cost associated with HCV treatment has yet to be determined. Long-term adverse events may arise in the coming years with greater numbers of persons treated. It will be important to use and monitor the FDA Sentinel System.
- States that have not introduced syringe services programs may have a large number of individuals with an increased risk for reinfection; thus, clinical and financial burden associated with HCV management of people who inject drugs (PWID) in these states may be higher.

Health Care System Capacity

- Identifying realistic goals for HCV treatment within systems–based on expected number of cases, current rates of diagnosis, and providers' capacities–would support planning efforts and set standards.
- Implementation of viral hepatitis quality measures, (e.g., HCV screening of all individuals born 1945–1965 and those at risk) would elevate the issue with providers and incentivize adoption of institutional and state guidelines.
- A systems approach is needed to address HCV, particularly for individuals with complex comorbid conditions.
- Multidisciplinary care is associated with improved patient outcomes and health care efficiencies, especially for individuals with complex health conditions.
- Activities to address the opioid epidemic, as well as substance abuse treatment models, should integrate HCV testing and treatment to mitigate the limited availability of dedicated HCV resources.
- Using existing safety and efficacy data may support payers to move away from specialist-driven treatment models and expand HCV treatment in primary care. Physician assistants (PAs), nurse practitioners (NPs), and clinical pharmacists have been shown to safely and effectively manage HCV treatment. Current state Medicaid policies regarding pharmacists' practice limitations and HCV treatment prescribing practices among all mid-level providers should be reviewed.
- Providers should develop clear processes and procedures to adequately assess and prepare patients and reinforce the importance of patient adherence to HCV treatment. Models of effective HCV treatment support should be identified and adopted to further improve outcomes.
- Additional models for optimizing HCV management are needed along with more widespread adoption of existing effective models, including:
    - Project ECHO at the University of New Mexico utilizes telecommunications technology to support knowledge transfer where resources are limited (e.g., remote geographical areas without specialty providers). Project ECHO supports a weekly clinic in which primary care providers (PCPs) from approximately 35 dispersed health centers learn and engage in best practices in HCV care. Provider

satisfaction is high and similar patient outcomes have been observed for patients treated by Project ECHO PCPs and specialists compared to patients treated through traditional approaches. This model has been replicated and expanded for HCV (currently 10 hubs exist) and translated for use to address other diseases.

  - The Cherokee Nation Health Service has expanded their HCV age cohort screening practices to include persons aged 20 to 69 to capture recent trends in new infections, as well as the baby boomer cohort. Patients are screened at a variety of settings (e.g., emergency rooms, behavioral health services, dental clinics) which has led to system-wide near-universal screening. Using a Project ECHO-like model, workforce capacity has increased and centralized case management and medication procurement has led to effective linkage to care and treatment. Efforts to screen all within the age cohort within 2 years remain underway, and future work will integrate HCV care with other care systems (e.g., behavioral health).
  - Project INSPIRE is a comprehensive care coordination project in New York City that receives funding from CMS Center for Medicare & Medicaid Innovation (CMMI). The program model is based on Project ECHO and includes telementoring, weekly integrated team meetings, care coordination, linkage to care specialists, and peer navigation. Evaluation is ongoing to determine if the program results in short-term cost savings as a result of patient pre-treatment HCV education and if the program is sustainable.
  - VA has implemented EHR clinical reminders for HCV screening that has resulted in more than 75% of patients in the birth cohort being screened for HCV. Furthermore, using local system redesign teams and data tools (e.g. clinical dashboards) to improve processes for HCV care delivery, use of mid-level providers (e.g., pharmacists, NP, etc.) to supervise DAA treatment, and inclusion of primary care providers in finding/educating/treating hepatitis C, the VA has treated more than 70,000 (>50%) of their patients with HCV since January 2014, with a >90% SVR rate.

- Project ECHO is fundamentally a provider training model and not a treatment model, therefore opportunities for reimbursement from traditional healthcare payer sources are limited. There is robust interest among PCPs in participating, even though the training requires additional time without compensation. This model should be assessed and reviewed to identify reimbursement options to sustain this capacity-building practice.
- More efforts should support primary care providers to implement current HCV screening recommendations, standards of care after diagnosis, and treatment options.
- Increasing HCV case management capacity in diverse provider settings (e.g., behavioral health) is needed. Many HCV patients require intensive levels of case management to

attain the best outcomes. Directly observed therapy treatment models should be explored.

- Leveraging specialty pharmacies can increase the number of patients on treatment per provider and promote financial sustainability.
- Savings resulting from participation in the 340B drug pricing program funding have been used to support case management and pharmacy efforts (including pre-authorizations) that can contribute to the effectiveness of management programs; however, the sustainability of the practice is unclear. It is important that states are up-to-date on forthcoming changes to the 340B program that transition it to an acquisition cost-based reimbursement to preclude duplicate discounts on drugs.
- Evaluating and communicating the cost of HCV treatment, particularly the non-medication costs, cost-effectiveness, and benefits will underscore the value of treatment and cure to payers and health systems, and inform an effective payer model.
- As the case of the VA has shown, special appropriations funding to treat HCV is critical to ending the epidemic in the United States.
- There may be an opportunity in the Ryan White HIV/AIDS Program to develop HCV treatment best practices and models for clients with HIV-HCV coinfection, which could also be used for monoinfected individuals.
- Federal-level programs are needed to support all steps along the HCV cure cascade.

HCV Screening

- Low HCV screening rates limit the number of persons who are aware of their HCV infection and are able to seek treatment early in the course of infection. Actions are needed to increase screening in health care and settings that serve persons at increased risk for HCV.
- Full coverage of HCV screening (including confirmatory and genotype testing) in all care settings under the ACA would further expand early HCV diagnoses. In particular, emergency department screening programs have been shown to yield a high number of diagnoses and should be explored further to determine effective linkage to care and treatment strategies.
- The increasing trend of opioid addiction and injection drug use should drive recommendations for an expanded age range for HCV screening (e.g., Cherokee Nation expanded their age cohort screening to include persons aged 20 to 69 due to a large number of young PWID).
- EHR prompts have shown to be effective in increasing HCV testing rates in health systems compared to risk assessment-based strategies. Further work to identify effective strategies using the EHR to increase screening and diagnosis of chronically infected persons is needed and should make use of data elements such as sexual and substance use history.

- Opt-out screening practices should be implemented. The requirement of verbal confirmation poses a barrier to screening acceptance; lab-triggered screening may avoid opt-out challenges and ensure that those at risk who are engaging with the health care system, for any reason, will be tested.

Next Steps

The availability of highly effective DAAs that cure HCV has dramatically transformed opportunities to improve health outcomes and to reduce liver disease, liver cancer, and death among people living with HCV. To realize the full potential of these new tools and make most efficient use of them, changes in policy, practice, education, and attitude are required. Specific factors that influence access to HCV treatment are the price of the DAAs, payer policies, health system capacity, patient and provider awareness, and attitudes about people with substance use disorders. An important perspective, which is not well understood or described, are patient experiences and the benefits patients experience after cure. Expediting systems change to facilitate more widespread HCV screening and treatment will require the support of many partners in the fight against HCV. In light of the rapidly changing landscape, it is clear that payers, health systems, and providers should review current policies, including their basis and rationale, and make any necessary modifications to bring them in line with the latest evidence.

There is an urgent need for up-to-date data on HCV prevalence, treatment effectiveness, the effectiveness of model programs/interventions, and insurance (coverage, limitations, and benefit design) in this rapidly changing field to effectively guide decision making by a variety of stakeholders. Identifying existing model policies and procedures that others are developing and implementing can support effective systems change through dissemination of innovations. Further engagement of federal partners, professional organizations, and leaders in the field of health care quality and innovation is needed with a focus on the issue of HCV treatment. These were among the actions discussed during the expert consultation to support organizations as they work to navigate the evolving landscape and expand access to these life-saving drugs to those who need them in the United States.

Appendix A: Agenda

Expert Consultation on the Evidence for Early Hepatitis C Treatment in the United States
Ford House Office Building
441 D Street, SW, Room 483
Washington, DC 20002

September 12-13, 2016

Purpose: Bring diverse stakeholders together to review and discuss the scientific evidence regarding the benefits and costs of early hepatitis C treatment, access to hepatitis C treatment, innovative models, challenges from public health, health care provider and payer perspectives, and possible opportunities to improve access and ultimately cure more people with chronic hepatitis C and reduce new infections in the United States.

DAY ONE	
12:30pm – 1:00pm	**Registration**
1:00pm – 1:10pm	**Welcome** *Karen DeSalvo, MD, MPH, Acting Assistant Secretary for Health, Department of Health and Human Services (HHS)* *Karen A. Scott, MD, MPH, Chief Medical Officer, Office of the Assistant Secretary for Health*
1:10pm – 1:30pm	**Orientation to the Meeting** *Richard Wolitski, PhD, Acting Director, Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)* *Corinna Dan, RN, MPH, Viral Hepatitis Policy Advisor, OHAIDP* • Background • Introductions • What we have and hope to accomplish
1:30pm – 2:00pm	**HCV Treatment Access in the United States: Needs vs. Reality** *Brian R. Edlin, MD, Chief Medical Officer, National Center HIV, Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention* • *New HCV treatment: opportunities* • *Treatment guidelines & benefits* • *Challenges & harms* • *Treatment policy & public health*
2:00pm – 2:30pm	**Societal Benefits of HCV Treatment** *Jagpreet Chhatwal, PhD, Senior Scientist, Institute for Technology Assessment, Assistant Professor, Harvard Medical School* • A brief review of what is known about the societal benefits of HCV treatment
2:30pm – 3:00pm	**Group Discussion** Moderator*: Corinna Dan* • Understanding and assessing the benefits of HCV treatment.
3:00pm – 3:15pm	***Break***

DAY ONE	
3:15pm – 3:30pm	**Center for Medicaid Services and HCV Treatment** *John Coster, PhD, RPh, Director, Division of Pharmacy, Center for Medicaid & CHIP Services, Centers for Medicare & Medicaid Services*
3:30pm – 4:15pm	**Working to Improve Access to HCV Treatment** *Kevin Costello, JD, Senior Associate Director and Litigation Director, Center for Health Law Policy Innovation, Harvard Law School* *Stacey Trooskin, MD, PhD, Director of Viral Hepatitis Programs, Philadelphia FIGHT Community Health Centers* • What is the cost of HCV treatment • Access and availability of HCV treatment • Facilitators and barriers to HCV treatment access
4:15pm – 5:00pm	**Panel Discussion:** Organizational Perspectives on HCV Treatment Challenges and Trends Moderator: *Michael Horberg, MD, MAS, Executive Director, Mid-Atlantic Permanente Research Institute* Discussants: *Colleen Flanigan, RN, MS, Director, Bureau of Hepatitis Health Care, New York State Department of Health* *Pamela Belperio, PharmD, National Public Health Clinical Pharmacist, Veterans Health Administration, Department of Veterans Affairs* *Kimberly Lenz, PharmD, Clinical Pharmacy Manager, Office of Clinical Affairs, Massachusetts State Medicaid*

DAY TWO	
8:30am – 8:40am	**Day One Highlights and Discussion Points** *Karen Scott*
8:40am – 9:10am	**HCV Cost Trends and Cost Effectiveness** *Benjamin Linas, MD, MPH, Assistant Professor of Medicine and Epidemiology, Boston University, Director HIV Epidemiology and Outcomes Research Unit, Section of Infectious Diseases, Boston Medical Center*
9:10am – 9:40am	**Focus on the Payer Perspective** *Steve Miller, MD, MBS, Senior Vice President & Chief Medical Officer, Express Scripts* • How payers make decisions about what to cover • Costs and benefits from the payer perspective • Challenges and gaps
9:40am – 10:30am	**Panel Discussion: Evolving HCV Treatment Access** Moderator: *Amy Killelea, JD, Director, Health Systems Integration, National Alliance of State and Territorial AIDS Directors* Discussants: *Elizabeth Raitz-Cowboy, MD, Medical Director, Southeast Region, Aetna* *Kate Berry, Senior Vice President, Clinical Affairs and Strategic Partnerships, America's Health Insurance Plans*
10:30am -10:45am	***Break***

DAY TWO	
10:45am – 11:30am	**Panel Discussion: HCV Effective Models of Care** • State and healthcare system approaches • Model programs Moderator: *Stacey Trooskin* *Discussants:* *Karla Thornton, MD, MPH, Associate Director, Project ECHO, The University of New Mexico,* *Jorge Mera, MD, Director Infectious Diseases, Cherokee Nation Health Service* *Shuchin Shukla, MD, MPH, Instructor, Department of Family and Social Medicine, Montefiore Medical Center*
11:30am – 12:15pm	**Panel Discussion: Implementing the Most Efficient and Effective HCV Treatment Programs** Moderator: *Corinna Dan* *Discussants:* *Sean Dickson, JD, MPH, Senior Manager, Health Systems Integration, National Alliance of State and Territorial AIDS Directors* *Jerry Ernst, MD, Chief Medical Officer, AmidaCare (NY)* *Timothy Morgan, MD, Chief of Hepatology, Department of Veterans Affairs Medical Center, Long Beach Healthcare System*
12:15pm – 1:30pm	***Lunch***
1:30pm – 2:15pm	**Data Gaps & Needs to Expand HCV Treatment Access** Moderator: Rich Wolitski *Group Discussion* • Surveillance/epidemiology • Health services/health systems • Systems for collecting local level information • Research
2:15pm – 3:00pm	**Policy Actions to Expand HCV Treatment Access** Moderator: Corinna Dan *Group Discussion* • Healthcare delivery • Payer • Strategies to reduce costs • Responding to trends & opportunities
3:00pm – 4:00pm	**Discussion: Next Steps and Wrap Up** Karen Scott and Rich Wolitski
4:00pm	**Adjourn**

Thank you to the Planning Committee for their hard work and support for this consultation.

John Coster, CMS
Martha Gerrity, Oregon Health & Science University
Michael Horberg, Kaiser Permanente
Amy Killelea, NASTAD
David Rein, NORC at the University of Chicago
David Ross, Department of Veterans Affairs

Appendix B- Participant List

Expert Consultation on the Evidence for Early Hepatitis C Treatment in the United States
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Washington, DC 20002

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