

## CER Questions

### Care Delivery

The following health systems questions fall into four major categories:

1. Improving diagnosis and treatment of HCV infected individuals through different care models that integrate primary and specialty care.
2. Improving medication adherence and patient outcomes through team versus individual practitioner treatment approaches
3. Improving primary care capacity to effectively screen and treat individuals infected with HCV through different settings of care, technology and health information, especially for high risk populations, such as intravenous drug users and HIV infected HCV patients.
4. Examining the impact of state coverage and screening policies on medication adherence, patient outcomes, drug resistance, and identification of HCV infected patients.

***1. What approaches for linking primary care physicians with specialty teams are most effective in accurately diagnosing and effectively treating patient with hepatitis C, particularly individuals in rural or medically underserved areas?***

**Importance of question:** There is a shortage of skilled healthcare professionals that can treat HCV. Many primary care physicians are unprepared to deal with HCV infected patients. The prevalence of HCV is disproportionately high in medically-underserved areas.

**Preliminary evidence:** Project ECHO (Extension for Community Healthcare Outcomes) is an example of a learning guided practice model that was launched in New Mexico where specialist teams trained in HCV diagnosis and treatment were linked via telecommunications to primary care doctors in underserved areas for weekly training sessions (echo.umn.edu). The vast majority of patients treated were Hispanic and the 21 community based settings included five prisons, thus demonstrating the success of the model for specific underserved and hard to reach populations. The project has received funding from the AHRQ (2011) and the Robert Wood Johnson Foundation. The model is diffusing and there are numerous publications demonstrating its success in New Mexico.

**Gaps in Knowledge:** How do other models compare to the success of Project ECHO in head-to-head or against well-defined usual care? How effective is a model like Project ECHO in other settings and targeting other populations (e.g., urban underserved)?

***2. What is the comparative effectiveness of various team-based approaches versus individual physician treatment to improve medication adherence and cure rates for patients diagnosed with hepatitis C? These may include: intensive case management; intermediate case management; multi-disciplinary clinical management approaches; pharmacy management models, comprehensive medication therapy management; cognitive behavioral therapy, patient navigation?***

- a. ***Which subpopulations are the most likely to benefit from these approaches? (e.g., patients at high risk of nonadherence versus those at moderate risk of nonadherence; patients with behavioral health issues and/or substance abuse disorders)***

**Importance of Question:** Medication adherence is critical for achieving a sustained virologic response, and ultimate cure for HCV, but the disease is concentrated in a population with chaotic lives and poor access to care, and may warrant novel approaches that combine approaches such as cognitive behavioral therapy with more traditional case management.

**Preliminary Evidence:** Medication therapy management and other multi-disciplinary approaches have been shown to improve medication adherence. Pharmacy management models may be especially interesting to test given the many models are already being supported by insurers and health plans, with several models already tested or currently being tested for the improvement of medication adherence in chronic disease populations (AHIP 2014).

**Gaps in Knowledge:** Low rates of medication adherence to HCV regimens have been documented with fully half of those who begin the course of treatment failing to complete it. Such failure, however, is understandable in light of the length, complexity, side effects and lower cure rates of past therapies (AHRQ 2009). The introduction of single pill therapy (e.g., Sovaldi) with minimal side effects, a substantially reduced period of required adherence from approximately 48 weeks to 12, and an 80% or higher cure rate may reduce patient failure rates with medication adherence for HCV. However, that is yet to be shown. In light of AHRQ's finding that 20-30% of prescriptions go unfilled, and that 50% who take them failing to do so in accordance with the recommended regimen, this concern is legitimate.

3. ***Which health care delivery approaches are most effective for screening and treating complex and hard to reach HCV infected individuals, such as the homeless, prison populations, intravenous drug abusers and HIV-infected individuals?***

**Importance of Question:** Intravenous drug use is a primary means of transmission of HCV in the US, but those who use drugs are typically difficult to reach, have significant co-morbidities, and have been understudied in phase 3 clinical trials. Notably, between 50 and 90% of injecting drug users infected with HIV are co-infected with HCV. Finally, depending on geographic area, the prevalence of HCV infection among the homeless has been found to be as high as 69 percent, with the HIV-positive homeless at particularly high risk of HCV infection (Chak 2011). These subpopulations often are poorly integrated into the formal health care delivery system. Prison population who also are at a disproportionate risk of HCV infection remain significantly underserved.

The National Business Group on Health (2013) urged AHRQ's USPSTF that screening must be conducted for individuals at risk for HCV in a systematic and targeted manner. Effective screening is a serious concern for the entire health system. An estimated 75% or more of the 3.2 million infected are unaware of their status, given that early HCV is often asymptomatic (CDC). Without effective screening of those at high risk, many will continue to seek treatment at advanced stages of the disease when it is too late to cure and expensive and complicated to treat.

**Preliminary Evidence:** AHRQ (2012) conducted a review of screening and treatment for HCV and found that “screening can accurately identify adults with the disease but more research is needed to understand the effects of targeted screening strategies in adults”, and “on the effects of knowing one’s HCV status on clinical outcomes.”

AHRQ (June 2013) also found that reminder stickers pasted onto patients’ medical charts that list risk factors for HCV can increase the number of patients referred for HCV testing by their PCPs.

Regarding outreach and treatment of prison and HIV populations, there are dedicated programs in place to address these hard to reach populations, such as methadone maintenance clinics and inpatient/outpatient addiction programs.

**Gaps in Knowledge:** Mechanisms to screen, monitoring, and treatment for individuals who do not have private insurance remain a significant gap in knowledge (IOM 2011). Comparing the effectiveness of non-traditional settings, such as methadone maintenance clinics or the use of a comprehensive harm-reduction strategy (needle exchange, education/counselling, medical care without requirement for discontinuation of drug use).

It should be noted that of the 3.2 million HCV infected, two out of three are of an age soon to enter the Medicare system (Gravitz 2011); thus, Medicare providers will need to be prepared to diagnose and treat this population. (Milliman 2009).

**4. *How do patient-centered outcomes (e.g., cure rate as measured by a sustained virologic response) for HCV patients enrolled in Medicaid programs with restrictive formularies for Hepatitis C medications (e.g., prior authorization requirements, step therapy requirements, non-coverage of selected medications, restrictions on combination therapy) or targeted eligibility criteria (e.g., biopsy proven fibrosis) compare with those enrolled in Medicaid programs with fewer restrictions?***

**Importance of Question:** HCV infection disproportionately affects low-income populations, many of whom are uninsured. With expansion under the Accountable Care Act, it is expected that many will be covered through the health insurance exchanges or Medicaid (Millman, 2013). Concerned about the potential impact on state budgets, state Medicaid programs and Medicaid managed care plans are limiting access to expensive medications to only the sickest patients (Governing 2014). There is variation across the programs in formularies, which allows for research to take advantage of natural experimentation.

**Preliminary Evidence:** The National Conference of State Legislatures tracks Medicaid prescription drug policies and strategies. To date, there has been no research examining state variation in Medicaid coverage policies for Hepatitis C medications and its impact on patient outcomes.

**Gaps in Knowledge:** In addition to the primary research question posed above, it may be of interest to examine differences in Medicaid strategies to monitor and demonstrate compliance with medications coupled with variation in coverage policies. Patient-centered outcomes, such as sustained viral response, will not be available in Medicaid claims data. Similarly, comparative



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effectiveness studies of variations in Medicaid coverage policies would require access to outcomes data which may not be accessible to patients on their own.