PCORI's Hepatitis C Workshop

Arlington, VA

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Patient-Centered Outcomes Research Institute

Plenary Session: Review and Discussion of Prioritized CER Questions

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Report Back from Breakout Sessions—Discussion of Ranked CER Questions

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Care Delivery

Gillian D. Sanders, PhD
Associate Professor of Medicine
Director, Duke Evidence Synthesis Group
Duke University and Clinical Research Institute

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Care Delivery CER Questions Presented to the Breakout Group

- Q1: What approaches for linking primary care physicians with specialty teams are most effective in accurately diagnosing and effectively treating patients with hepatitis C, particularly individuals in rural or medically underserved areas?
- Q2: 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?
  - 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)

Care Delivery CER Questions Presented to the Breakout Group (cont.)

- Q3: Which healthcare 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?
- Q4: 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?

Care Delivery CER Questions Ranked Highest by the Breakout Group

- Q1: 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?

  Support from the following stakeholder groups: clinicians (7), industry (3), payers (2), purchasers (1), systems (3)

- Q5 (1-3): What is the comparative effectiveness of available healthcare delivery approaches for reaching, screening, assessing disease, treating, and preventing new infections and reinfections of Hepatitis C?

  Support from the following stakeholder groups: clinicians (5), industry (5), patients (3), purchasers (1), researchers (3)

Screening and Diagnostic Tests

John Wong, MD
Chief, Division of Clinical Decision Making
Tufts Medical Center

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Screening and Diagnostic CER Questions Presented to the Breakout Group

- Q1: What are the comparative benefits and risks of non-invasive tests for liver fibrosis in staging patients with hepatitis C?
- Q2: a. Compare the conventional two-step screening and confirmation protocol (anti-HCB Ab followed by HCV polymerase chain reaction [PCR] if positive) with a “reflex test” (in which anti-HCB Ab is followed by “reflex” HCV PCR if the antibody test is positive).
- b. Compare the impact of rapid anti-HCV Ab with “conventional” testing on the outcome of informing the screened people of their HCV status
- Q3: What are the harms and benefits of different methods to identify people at high risk of contracting hepatitis C?

Screening and Diagnostic Highest Ranked CER Questions by the Breakout Group

- Q2: Compare the response rate to rapid antibody test v reflex test v "conventional" testing on the outcome of linkage to care and patient satisfaction.

  Support from the following stakeholder groups: clinicians (2), federal (4), patients (1), systems(1)

- Q3: Which screening methods have the highest linkage to care? Which methods work best in which settings?

  Support from the following stakeholder groups: clinicians (2), federal (5), patients (1), systems (2)

Head-to-Head Trials

Camilla Graham, MD
Assistant Professor of Medicine
National Viral Hepatitis Roundtable

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Head-to-Head Trials CER Questions Presented to the Breakout Group

- Q1: Which of two all-oral interferon-free strategies for the treatment of chronic genotype 1 hepatitis C infection, including sofosbuvir/ledipasvir and paritaprevir/ritonavir/ombitasvir/dasabuvir +/- ribavirin, will maximize sustained virologic response (SVR) and minimize adverse effects and harm?
- Q2: Which of the available therapies - existing and recently introduced - for treatment of Hep C demonstrate the best outcomes with the fewest side effects?
- Q3: Would those failing one DAA-based combination regimen respond to another regimen?
- Q4: What are the real-world rates of reinfection, particularly among IV drug users?

Head-to-Head Trials CER Questions Ranked Highest by the Breakout Group

- Q1: Which of two all-oral interferon-free strategies for the treatment of chronic genotype 1 hepatitis C infection, including sofosbuvir/ledipasvir and paritaprevir/ritonavir/ombitasvir/dasabuvir +/- ribavirin, will maximize sustained virologic response (SVR) and minimize adverse effects and harm?

  Support from the following stakeholder groups: clinicians (5), coalition (4), federal (2), patients (4), payers (2), researchers (2), systems (1)

- New Question: Is there a benefit to treating early-stage patients?

  Support from the following stakeholder groups: clinicians (3), federal (2), patients (3), payers (2), researchers (2), systems (1)

Patient Populations and Timing of Treatment

Martha Gerrity, MD, MPH, PHD
Clinical Evidence Specialist
OHSU/Drug Effectiveness Review Program

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Patient Populations and Timing of Treatment CER Questions Presented to the Breakout Group

- Q1: What are safety profile and effectiveness of HCV therapy in specific patient populations?
- Q2: What are the comparative benefits and harms of treating all patients with HCV infection versus waiting to treat only those patients who show signs of liver disease? What level of severity of liver disease should be used as the basis to indicate beginning antiviral therapy?
- Q3: Does treating HCV help in the management of identified comorbidities, e.g., diabetes mellitus, cardiovascular disease, chronic kidney disease?
- Q4: Can antiviral therapy reduce transmission of hepatitis C? Should an attempt be made to eradicate hepatitis C in IV drug users? What interventions can reduce transmission of hepatitis C?

Patient Populations and Timing of Treatment CER Questions Ranked Highest by the Breakout Group

- Q1: What are safety profile and effectiveness of HCV therapy in specific patient populations?

  Support from the following stakeholder groups: clinicians (2), patients (8), industry (3), researchers (3), payers (2)

- Q2: What are the comparative benefits and harms of treating all patients with HCV infection versus waiting to treat only those patients who show signs of liver disease? What are the predictive factors or models that help determine risk of progression of disease?

  Support from the following stakeholder groups: researchers (4), patients (4), industry (8), payers (5), clinicians (2)

- Q3: In difficult-to-treat patients, does treating hepatitis C help in the management and treatment of comorbidities such as diabetes mellitus, cardiovascular disease, chronic kidney disease, renal transplant, and HIV infection?

  Support from the following stakeholder groups: researchers (1), industry (5), payers (1)

Top-Ranked Prioritized CER Questions
(second round of prioritizing across entire workshop)

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Head-to-Head Treatment Comparisons

- Which of two all-oral interferon-free strategies for the treatment of chronic genotype 1 hepatitis C infection, including sofosbuvir/ledipasvir and paritaprevir/ritonavir/ombitasvir/dasabuvir +/- ribavirin, will maximize sustained virologic response (SVR) and minimize adverse effects and harm?

  Support from the following stakeholder groups: federal (2), patients (5), systems (1), clinicians (2), researchers (1), payers (1)

Head-to-Head Treatment Comparisons (Combination of two breakout questions)

- Is there a benefit to treating early stage patients? (Head-to-head breakout group)

AND

- What are the comparative benefits and harms of treating all patients with HCV infection versus waiting to treat only those patients who show signs of liver disease?

  (Patient population and timing of treatment breakout)

Support from the following stakeholder groups: federal (3), clinicians (2), researchers (3), payers (8), purchasers (1), industry (5)

Care Delivery

- What is the comparative effectiveness of available healthcare delivery approaches for reaching, screening, assessing disease, treating, and preventing new infections and reinfections of Hepatitis C?

  Support from the following stakeholder groups: industry (2), patients (6), clinicians (2), purchasers (1)

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

  Support from the following stakeholder groups: industry (1), systems (1), clinicians (3), researchers (1)

Screening and Diagnosis Tests

- Which screening methods and testing strategies in which settings lead to the best outcomes?

Support from the following stakeholder groups: federal (4), patients (1), industry (2), researchers (6)

Closing Remarks

Bryan Luce, PhD, MBA
Chief Science Officer, PCORI

David Hickam, MD, MPH
Program Director, Clinical Effectiveness Research, PCORI

Harold Sox, MD
Senior Adviser, PCORI

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Adjournment

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