

PIPC: Hepatitis Roundtable Summary and Recommendations on Dissemination and Implementation of Clinical Evidence

On May 8, 2014, the Partnership to Improve Patient Care (**PIPC**) convened a Roundtable of experts in the diagnosis, treatment, and care of patients with hepatitis B (**HBV**) and C (**HCV**): i.e., patient advocates, health care providers (nurse practitioners, physician specialists including family physicians, gastroenterology, infectious disease, and oncology), representatives from the Department of Health and Human Services (**HHS**), and the Patient-Centered Outcomes Research Institute (**PCORI**), all of whom participated individually and/or on behalf of their representative organizations, to discuss current challenges to and potential solutions for the appropriate dissemination and implementation of clinical evidence. Additionally, this group focused on the value and clinical benefits of ensuring patients and providers have access to reliable, relevant, current data and information.

Building on an earlier PIPC Roundtable focused on gastrointestinal disorders, expert stakeholders, including patients and providers, identified hepatitis as a clinical area with significant opportunities to improve patient care through appropriate communication and implementation of evidence-based research. Therefore, by focusing on recent advances in screening and treatment for HBV and HCV, this Roundtable hoped to accomplish two goals:

1. Present PCORI with creative approaches and options to inform PCORI's development of a Dissemination and Implementation Action Plan;
2. Highlight broader practice and policy issues related to clinical and societal value in providing patients and their providers with access to useful clinical and health care information and messages that will help them make informed health care decisions leading to better patient health outcomes.

PCORI's Role in Dissemination and Implementation

The Patient Protection and Affordable Care Act (**ACA**) created a new context for comparative effectiveness research that is to be prioritized, conducted, and communicated in ways that are patient-centered and focused on answering questions that are important to patients and providers. To support those principles, Ms. Jean Slutsky, Chief Engagement and Dissemination Officer at PCORI, began the discussion by reviewing the goals and approaches of the PCORI's Dissemination and Implementation initiative for the participants. She also highlighted how the groups represented might collaborate with PCORI in identifying and studying the comparative effectiveness of dissemination and implementation models that most effectively inform patients and providers about emerging screening and treatment options for patients with HBV and HCV.

A key mandate on PCORI is to change the culture of research to ensure that research findings are disseminated and appropriately implemented in a manner that changes practice behaviors and improves patient outcomes. Recognizing the challenges and barriers to achieving this goal, including defining the behaviors that need to be addressed, the clinical information meant to support change, and the audiences that would benefit from that information, PCORI continually seeks to fund studies addressing questions critical to both individuals and the health care

community with the goal of generating clinical evidence to help inform patient and provider health care decisions. The following summary captures the views of Roundtable panelists in terms of: 1) what factors must first be addressed and what challenges must be overcome in order for appropriate dissemination and implementation of evidence to occur; and 2) the clinical benefits for patients and the societal value gained by ensuring patients and providers have access to evidence-based information to support informed decision making.

Challenges and Opportunities in the Dissemination and Implementation of Evidence

The Complexity of Primary Care

Although many hepatitis patients will be referred to a hepatologist or infectious disease specialist, the importance of the primary care encounter in managing the full continuum of care surfaced early in the discussion and proved a recurrent theme. Prior to establishing appropriate dissemination and implementation strategies, participants first highlighted the inherent challenges in primary care. Primary care providers experience enormous time constraints and often time reimbursement and payment designs do not account for “care management”, instead focusing on quantity of services provided. Therefore, the first step to guarantee primary care providers can appropriately disseminate and implement evidence is to ensure efficient mechanisms are available to help providers identify and effectively manage treatment.

One such mechanism that was discussed was the use of electronic medical records (EMRs) in order to identify populations at higher risk for HBV and HCV. However, pragmatic and technical challenges surfaced early in a discussion of the difficulties of disseminating and implementing care via an EMR, including certain public perception, policy, and ultimately funding issues. Among the practical steps recommended to address these challenges was greater collaboration with the major EMR providers to incorporate screening modules in their software; however this prompted comments from primary care representatives about the risk of ‘alert fatigue’ stemming from the constant array of alerts which may or may not have a meaningful impact on care and may consume an entire primary care visit.

As the conversation progressed, it became evident that primary care engagement is a systemically important element in implementing successful screening, prevention and treatment of diseases. Effective communication of sound evidence for patients and their caregivers requires a relationship with a trusted healthcare professional with the information, resources, financial and delivery system support to engage with the patient. Participants noted the need to craft sustainable models to encourage primary care practices to appropriately manage disease, including the screening, testing and treatment for hepatitis. Proposals included:

- Incorporate recommended screenings into the broader systems of care that support provider engagement with patients throughout the care continuum;
- Appropriate use of EMRs and clinical decision support tools;
- Require appropriate dissemination and implementation of screening/treatment recommendations when evaluating provider performance; and

- Include screening and treatment recommendations in quality measures, such as the PQRS reporting systems.

In addition to more efficient technical mechanisms and systemic incentives, participants also highlighted the need for a *“team approach”* marshalling multidisciplinary resources to best manage the continuum of care. Specifically mentioned as key were physician assistants, nurse practitioners, nurses, physicians, community pharmacists, and patients. Participants also stressed the importance of collaboration with provider organizations to ensure that primary care physicians and members of the extended care team were true partners, to avoid the image of the condescending specialist.

Lastly, it was noted that primary care physicians may feel the lack of treatment options for certain conditions which may act as a barrier to screening, testing and/or prescribing treatment. Roundtable participants highlighted the importance of appropriate models of disseminating evidence, suggesting that access to evidence which informs them of preventive and treatment options would better assist them in implementing evidence-based practices.

Addressing Disparities, Special Populations, and Unique Opportunities

The discussion also highlighted the challenge of developing evidence that incorporates disparities and social determinants across subpopulations. Participants noted that hepatitis patients represent diverse populations including most, if not all, PCORI priority sub-groups, and receive care in settings that range from correctional institutions to community health and academic medical centers. It was raised during the discussion that while PCORI clearly has a role in this arena, there are multiple agencies with potential interest approachable by advocates, including the Centers for Disease Control and Prevention (**CDC**), Office of Minority Health (**OMH**) and Center for Medicare and Medicaid Services (**CMS**).

Participants also noted that although PCORI, by statute, seemed suited to engage in community participatory research and conduct comparative effectiveness studies to evaluate the efficacy of various methods to communicate with provider and patient communities in varied settings, more could be done. Racial and ethnic communities and other special populations should also have access to planning, decision-making capacity, funding and other services and tools to adequately address and implement evidence-based research.

Integrated into this discussion of special populations and related opportunities was the need to match patients with researchers, assuring that the research community has access to relevant patients thereby increasing the likelihood that studies will be designed to reflect “real world”, patient-centered realities. Conversely, participants stated that it is also vital to recruit reviewers with an appreciation for patient-centeredness and effectiveness, which was highlighted as a weakness of existing research processes. In sum, participants reiterated that it is critically important to conduct research on the best ways to reach varied populations (patients and clinicians) in order to identify what outcomes matter to them to better identify and change behaviors.

Understanding the Value of Disseminating and Implementing Sound Evidence

While understanding that there are certain barriers and challenges that exist in ensuring uptake of evidence, whether comparative effectiveness research (CER) generated by PCORI or research produced by other institutions, participants uniformly agreed that there is value in the appropriate dissemination and implementation of evidence. Specifically, the discussion highlighted the potential value to patients with chronic diseases where screening or treatment recommendations (and other clinical evidence) exist.

However, participants did note that in order to actively encourage the provision of high-value care, there must be data evaluating therapies from a broad societal perspective over extended time periods. This model, with consideration of long term benefits, already exists and is accepted in managing hypertension and diabetes and is likewise the way to most accurately develop the true value proposition for other therapies.

Participants noted that continued work is needed to continue to engage and align the priorities of government agencies and officials (public health commissioners and governors), advocates, insurers (public and private), and provider organizations that will serve to increase participation in and outcomes stemming from patient-centered research. With the ongoing implementation of the ACA, there is increasing demand for sound, clinical information and the need for mechanisms to disseminate and implement evidence-based research. An example of such clinical information is the recent Agency for Healthcare Research and Quality (AHRQ) Monograph [“Screening for Hepatitis C Virus in Adults.”](#)

Case Study: Dissemination and Implementation of Evidence related to Hepatitis B and C

By first stating and understanding the challenges and opportunities, and highlighting the value, of appropriate dissemination and implementation of evidence, the group used the current landscape in the treatment of hepatitis as an example of the challenges, yet significant value of disseminating and implementing clinical evidence for screening and treating hepatitis.

There are now updated U.S. Preventive Services Task Force (USPSTF) recommended guidelines for HBV and HCV screening, which clearly highlight the inherent systemic challenges that participants raised. The underlying questions that faced the group were: 1) how do we encourage and support primary care physicians to adhere to those guidelines, and 2) how do we assure that there is a transition from screening to effective management?

The participants, specifically primary care physicians, noted that the recommendations highlighted above could be applied to improve the dissemination and implementation of available evidence on screening/treatment of hepatitis. For example, dissemination of the USPSTF HCV screening recommendations could be implemented through effective inclusion in EMR systems. Assuming “alert fatigue” could be addressed, having easy access to the recommended clinical guidelines would make implementation of research results and recommendations much easier. Providers could expect an increase in patients with HCV being screened and ultimately receiving appropriate treatment. Additionally, having access to all

relevant and sound evidence would help physicians better manage care for their patient; allowing them to better coordinate patient care across the full continuum of care. Ultimately, primary care physician participants understood that, in the case of HCV, there are not only recommended screening guidelines, but also an ultimate treatment/cure.

The hepatitis example also exemplifies the need to have appropriate models of dissemination and implementation of evidence and the value it brings. Specifically in the case of HCV, there is significant value for patients treated and cured of this chronic, progressive, disabling, and potentially lethal infection, while also avoiding the costs (for patients and society) and profound morbidity of progressive and more widely disseminated liver disease. Participants noted that even in simple dollar terms, the cost per cure of the new regimen for HCV is less than the cost/cure of current regimens, emphasizing the importance of appropriate dissemination and implementation of new screening and treatment evidence for HCV. The participants noted that dissemination of information about the seriousness of the problem and the potential of new medicines to relevant stakeholders: patients, providers and policy makers, are critical challenges currently facing the advocacy community.

Hepatitis B-Specific Issues

Because of fundamental differences between HBV and HCV, issues specific to HBV infection were independently addressed. Among the issues that result in unique challenges and barriers in the dissemination and implementation of clinical evidence are a broad age range, specific racial and ethnic risk groups leading to disparities (especially among Asian & African immigrant communities with attendant language, cultural, and immigration status considerations), and payment challenges for a currently incurable disease requiring continuing treatment. As an example, it was noted that patient instruction sheets for HBV might be covered by editions in ten or more languages. In addition to the complexity and expense of accounting for variation in language, the associated health literacy issues also creates barriers to care in the primary care setting.

Creative screening models were mentioned as potential tools to enhance uptake of recommended screening guidelines for these groups, especially models that do not require seeing a physician. Examples included coupons distributed at health fairs offering free HBV screenings; and providing additional financial incentives to receive the screening (i.e., offering a Metrocard). Another concept received enthusiastically was delivering screening in “real” (e.g. not office) settings where supportive community members will likely be present. The related concept of a health coach, patient navigator or peer counselor also emerged as an idea that has worked in other disorders and could be effective in hepatitis. This is especially critical for newly insured (ACA-enabled) patients with challenging lives who may, ironically, risk losing access to needed therapy as a result of higher out-of-pocket costs and the loss of benefits from established assistance programs due to presumptive expanded access to coverage.

The participants noted that researching methods on how best to improve screening for HBV can be a role for PCORI, suggesting the Institute might support research evaluating different “direct

to patient” approaches using methodologically sound comparative effectiveness techniques to evaluate different methods of influencing behavior.

Conclusion

In concluding the Roundtable, participants reiterated the underlying theme of the discussion: highlighting the challenges and barriers to appropriately disseminating and implementing clinical evidence, while also addressing the value effective communication and application of clinical recommendations can have to both the individual patient and to society.

By using the current clinical hepatitis environment as an example, participants were able to demonstrate existing challenges (i.e., no efficient mechanisms for primary care physicians to receive evidence and inadequate payment for appropriately managing all aspects of care) and offer potential opportunities (i.e., effective and efficient EMR systems, financial incentives, quality measurement) in ensuring appropriate dissemination and implementation of evidence, all with the purpose of improving patient outcomes.

For PCORI, the participants highlighted certain areas which the Institute may study in order to provide more evidence about the effectiveness of various dissemination and implementation methods. These included:

- Evaluating the role of EMR vendors in developing, encouraging adoption of, and tracking these models and potentially comparatively evaluating them;
- Developing and studying models linking screening and successful treatment in hepatitis;
- Research on delivery system interventions and care management models (e.g., patient-centered medical homes) that promote patient-provider engagement based on sound evidence and clinical guidelines; and
- Conducting comparative analysis of different applications designed to change both physician and patient behavior.

For policymakers, the participants focused on the need and inherent value of providing physicians and patients with useful, clinical evidence that will help inform decision-making. In the context of hepatitis, the participants noted the clear clinical benefit for providers to conduct screenings, as recommended by USPSTF, and the short and long-term value of ensuring patient access to appropriate treatment following the screening.

Key Summary Points and Issues Requiring Study and Comparative Effectiveness Analyses

- PCORI’s Dissemination and Implementation mandate is potentially quite broad; among the challenges in hepatitis therapy include further defining:
 - Information to be disseminated;
 - Lifestyle choices and behaviors requiring modification;
 - Efficacy of therapy and factors affecting adherence;

- Broader audiences to be addressed - including specific racial and ethnic populations with special needs.
- PCORI will adhere to rigorous methodology while concurrently seeking to address these challenges from a customer (patient and provider-centric) perspective. This approach demands creative approaches and requires carefully designed, statistically relevant, and clear metrics for studying an array of communications, health literacy, racial and ethnic disparities and population groups, practice design, and alliance-building interventions. Importantly for grant seekers, PCORI is interested in initiatives that test, not those that design applications. Given the time pressure on PCORI, priority should be afforded to studies with the potential to complete in shorter time periods.
- The Primary Care Physician and Primary Care Encounter are critical; attention must be paid to resource constraints (including time constraints), motivations, capabilities, and practice stresses in the design of any and all screening and therapeutic efforts. Considerations for study and comparative effectiveness analyses, both for PCORI and other research funders, include:
 - Expanded capabilities and appropriate modifications in software (EMRs);
 - Redesigned incentives, including expansion of quality metrics/payment;
 - Expanded engagement of ancillary providers;
 - Design and test systems designed to manage hepatitis comprehensively in the primary care setting; need clear order sets and practice guidance;
 - Collaborate with primary care professional organizations to facilitate engagement with primary care physicians, ancillary providers and other relevant specialties.
- For policymakers and stakeholders more generally, it is important to recognize that diagnostic and treatment advances with higher initial costs can reduce longer-term costs (and in the case of HCV, cost per cure) for hepatitis patients, and to advance guidelines that optimize disease screening and treatment:
 - Support research to further demonstrate testing and therapy (for HCV with new agents) lowers actual cost per cure;
 - Evaluate value of treatment over time by integrating the cost of long term morbidity and mortality (liver transplant and hepatocellular carcinoma), and support infrastructure for eliciting and evaluating outcomes that matter to patients;
 - Resolve payment and delivery system issues to assure patient-centered access to treatment and to ensure that primary care providers understand the value of screening and that they can effectively manage patient treatment on their own or with the support of an extended care team;
 - Design and evaluate programs that increase access of racial and ethnic populations to screening and treatment—especially important given the expanded access implied by the ACA;
 - Promote provider care delivery models, including primary care and multi-disciplinary approaches, to support effective patient engagement and dissemination of evidence-based screening and evidence-informed treatment;



- Work with CMS and the National Quality Forum (**NQF**) to incorporate HBV and HCV care measures into quality initiatives (e.g., CMS' Meaningful Use and Physician Quality Reporting System (**PQRS**)).

Signed:

American College of Osteopathic Family Physicians
California Academy of Family Physicians
CanLiv: The Hepatobiliary Cancers Foundation
Caring Ambassadors Program, Inc.
Global Liver Institute
Hepatitis B Foundation
Hepatitis Foundation International
Interstate Postgraduate Medical Association
National Viral Hepatitis Roundtable
Partnership to Improve Patient Care