



This document is scheduled to be published in the Federal Register on 04/26/2012 and available online at <http://federalregister.gov/a/2012-10011>, and on FDsys.gov

Billing Code: 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Local Therapies for
Unresectable Primary Hepatocellular Carcinoma

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of local, minimally invasive, medical devices for unresectable primary hepatocellular carcinoma (e.g., ablation, radiotherapy, or embolization devices). Scientific information is being solicited to inform our Comparative Effectiveness Review of Local Therapies for Unresectable Primary Hepatocellular Carcinoma, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

DATES: Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

Online submissions:

<http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/>. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

E-mail submissions: ehcsrc@ohsu.edu (please do not send zipped files - they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239-3098.

FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Research Librarian, Telephone: 503-494-0147 or Email: ehcsrc@ohsu.edu.

SUPPLEMENTARY INFORMATION:

In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for local therapies for unresectable primary hepatocellular carcinoma.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the

literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the Federal Register and direct postal and/or online solicitations. We are looking for studies that report on local therapies for unresectable primary hepatocellular carcinoma, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: <http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=1012&pageaction=displayproduct#5056>

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The Key Questions

Question 1

What is the comparative effectiveness of the various liver-directed therapies in patients with hepatocellular carcinoma (HCC) who are not otherwise candidates for surgical resection or transplantation with no evidence of extrahepatic disease regarding survival and quality of life?

Question 2

What are the comparative harms of the various liver-directed therapies in patients with HCC who are not otherwise candidates for surgical resection or transplantation with no evidence of extrahepatic disease regarding adverse events?

Question 3

Are there differences in comparative effectiveness of various liver-directed therapies in patients with HCC who are not otherwise candidates for surgical resection or transplantation for specific patient and tumor characteristics, such as age, gender, disease etiology, and Child-Pugh score?

Dated: April 19, 2012

Carolyn M. Clancy,
AHRQ, Director

[FR Doc. 2012-10011 Filed 04/25/2012 at 8:45 am; Publication Date: 04/26/2012]