EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	80	7	[a] 47.34	$331
Health Plan Information Form	80	160	[a] 47.34	7,574
Data Use Agreement	60	3	[b] 85.02	255
Data Files Submission	80	320	[c] 37.63	12,042
Total	300	490	NA	20,202

* National Compensation Survey: Occupational wages in the United States May 2012, "U.S. Department of Labor, Bureau of Labor Statistics."
[a] Based on the mean hourly wage for Medical and Health Services Managers (11–9111).
[b] Based on the mean hourly wage for Chief Executives (11–1011).
[c] Based on the mean hourly wages for Computer Programmer (15–1131).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 8, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013–19712 Filed 8–13–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Imaging Techniques for the Surveillance, Diagnosis, and Staging of 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 the public on imaging techniques for the surveillance, diagnosis, and staging of hepatocellular carcinoma. Scientific information is being solicited to inform our review of *Imaging Techniques for the Surveillance, Diagnosis, and Staging of 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 imaging techniques for the surveillance, diagnosis, and staging of hepatocellular carcinoma will improve the quality of this review. AHRQ is conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before September 13, 2013.

ADDRESSES:

Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/. Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: SIPS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–220–8262 ext. 58652 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for *Imaging Techniques for the Surveillance, Diagnosis, and Staging of 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 requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on imaging techniques for the surveillance, diagnosis, and staging of hepatocellular carcinoma, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1600#7839*

This notice is to notify the public that the EHC program would find the following information on imaging techniques for the surveillance, diagnosis, and staging of hepatocellular carcinoma helpful:

- A list of completed studies your company has sponsored for this indication. In the list, *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including 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 follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

▪ *A list of ongoing studies your company has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

▪ Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site 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 email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1600#7839*

Key Question 1

What is the comparative effectiveness of available imaging-based surveillance strategies (listed below under interventions for KQ 1), used singly or in sequence for detecting hepatocellular carcinoma (HCC) among individuals undergoing surveillance for HCC (individuals at high risk for HCC and individuals who have undergone liver transplants for HCC)?

a. What is the comparative test performance of imaging-based surveillance strategies for detecting HCC?

i. How is a particular technique's test performance modified by use of various reference standards (e.g., explanted liver samples, histological diagnosis, or clinical and imaging followup)?

ii. How is the comparative effectiveness modified by patient-level characteristics (e.g., body mass index, number of lesions, tumor diameter, or cause of liver disease) or other factors (e.g., technical aspects of imaging techniques, biomarker levels, test operator or interpreter skill, setting)?

b. What is the comparative effectiveness of imaging-based surveillance strategies on intermediate outcomes like diagnostic thinking?

c. What is the comparative effectiveness of imaging-based surveillance strategies on clinical and patient-centered outcomes?

d. What are the adverse effects or harms associated with imaging-based surveillance strategies?

Key Question 2

What is the comparative effectiveness of imaging techniques (listed under the interventions for KQ 2), used singly, in combination, or in sequence in diagnosing HCC among individuals in whom an abnormal lesion has been detected while undergoing surveillance for HCC (individuals at high risk for HCC and individuals who have undergone liver transplants for HCC) or through the evolution of symptoms and abdominal imaging done for other indications?

a. What is the comparative test performance of imaging techniques for diagnosing HCC?

i. How is a particular technique's test performance modified by use of various reference standards (e.g., explanted liver samples, histological diagnosis, or clinical and imaging followup)?

ii. How is the comparative effectiveness modified by patient-level characteristics (e.g., body mass index, number of lesions, tumor diameter, or cause of liver disease) or other factors (e.g., technical aspects of imaging techniques, biomarker levels, test operator or interpreter skill, setting)?

b. What is the comparative effectiveness of the various imaging techniques on intermediate outcomes like diagnostic thinking and use of additional diagnostic procedures such as fine-needle or core biopsy?

c. What is the comparative effectiveness of the various imaging techniques on clinical and patient-centered outcomes?

d. What are the adverse effects or harms (related to testing or a test-associated diagnostic workup) associated with the various imaging techniques?

Key Question 3

What is the comparative effectiveness of imaging techniques (listed under the interventions for KQ 3), used singly, in combination, or in sequence in staging HCC among patients diagnosed with HCC?

a. What is the comparative test performance of imaging techniques to predict HCC tumor stage?

i. How is a particular technique's test performance modified by use of various reference standards (e.g., explanted liver samples, histological diagnosis, or clinical and imaging followup)?

ii. How is the comparative effectiveness modified by patient-level characteristics (e.g., body mass index, number of lesions, tumor diameter, or cause of liver disease) or other factors (e.g., technical aspects of imaging techniques, biomarker levels, test operator or interpreter skill, setting)?

b. What is the comparative test performance of imaging techniques on diagnostic thinking?

c. What is the comparative effectiveness of imaging techniques on clinical and patient-centered outcomes?

d. What are the adverse effects or harms associated with using imaging techniques related to testing or test-associated diagnostic workup?

PICOTS (Population(s), Interventions, Comparators, Outcomes, Timing, Settings) by Key Question

Population(s)

- Key Question 1.
  - Patients at high risk for HCC undergoing surveillance. The population of high-risk patients is defined, as per the AASLD clinical guidelines, as composed of the following: Asian male HBV carriers over age 40, Asian female HBV carriers over age 50, HBV carriers with a family history of HCC, African/North American black HBV carriers, all individuals with cirrhosis (including alcoholic cirrhosis), HBV or HCV carriers with cirrhosis, and patients with stage 4 primary biliary cirrhosis.6 Other definitions of high-risk patients as defined by the primary studies will be accepted.
  - Patients who have undergone liver transplants for HCC, either with or without HCC detected in the explanted liver.
  - Both population groups will be considered separately.
- Key Question 2.
  - Patients at high risk for HCC in

whom a suspicious lesion(s) has been detected by surveillance or by other means.
- Patients who have undergone liver transplants for HCC, either with or without HCC detected in the explanted liver.
- Both population groups will be considered separately.

- Key Question 3
  - Patients diagnosed with HCC who require staging before initial treatment.
- All Key Questions
  - Patients with cholangiocarcinoma will be excluded.

Interventions

- Key Question 1
  - US, spiral CT, multidetector CT (MDCT), dual energy CT, or MRI.
  - Studies that included surveillance strategies of any other imaging test with or without additional biomarkers would also be included. The strategies could include the techniques being used singly or in a specific sequence.
- Key Question 2
  - Imaging techniques, used singly, in combination, or in a specific sequence, including US, spiral CT, MDCT, dual energy CT, MRI (including contrast agents like Gd-EOB–DTPA and SPIO), or fluorodeoxyglucose positron emission tomography (FDG–PET) with different tracers (including 18F, fluorothymidine [FLT], 11C-choline, and 11C = methionine, or others).
- Key Question 3
  - Imaging techniques, used singly, in combination, or in a specific sequence, including US, spiral CT, MDCT, dual energy CT, MRI with contrast (including contrast agents such as Gd-EOB–DTPA and SPIO), FDG–PET with different tracers (including 18F, FLT, 11C-choline, and 11C-methionine, or others), or contrast CT.
  - Test performance of imaging techniques will be stratified by the different staging systems used.
- All Key Questions
  - Outdated imaging techniques (e.g., conventional, nonspiral/nonmultidetector CT, or imaging techniques used before 1995) will be excluded.
  - Imaging techniques not available or in use in the United States (e.g., hepatic portography) will be excluded.

Comparators

- For studies of diagnostic accuracy (comparative test performance), the reference standard comparators will be histopathology (based on explanted liver specimens or biopsy) or clinical and imaging followup, and the imaging comparators will be alternative imaging tests or strategies.
- For studies of comparative effectiveness, the comparators will be no imaging or alternative imaging strategies.

Outcomes for Each Key Question

Key Question 1
- Diagnostic outcomes include:
  - Detection rates of HCC lesions.
  - Types of HCC lesions detected.
  - Test performance (e.g., sensitivity and specificity, predictive values, likelihood ratios, area under the receiver operating curve, or others) for diagnosing HCC, including stage-specific accuracy.
  - For all KQs, potential modifiers of measures of test performance will be evaluated, including the reference standards used (e.g., explanted liver samples, histological diagnosis, or clinical and imaging followup), patient and tumor-level characteristics (e.g., body mass index, number of lesions, tumor diameter, or cause of liver disease), or other factors (e.g., technical aspects of the imaging techniques, biomarker levels, test operator or interpreter skill, setting).
- Intermediate outcomes include:
  - Effects on diagnostic thinking.
- Effects on clinical decisionmaking.
  - Clinical and patient-centered outcomes include:
  - Overall mortality or survival.
  - Recurrence of HCC, including rates of seeding by fine-needle aspiration.
  - Quality of life as measured with scales such as the Short-Form Health Survey (SF–36) or EuroQol 5D (EQ–5™) or as defined by the primary studies.
  - Psychosocial effects of diagnostic testing on patients, patients' caregivers, and other family members, as measured by self-reported questionnaire instruments.
  - Resource utilization and patient burden (e.g., costs associated with the imaging procedure, access to the imaging facility, the number of imaging procedures, and other procedures conducted).

Key Question 2
- Diagnostic outcomes include:
  - Type of HCC lesions detected.
  - Test performance (e.g., sensitivity and specificity, predictive values, likelihood ratios, area under the receiver operating curve, or others) for diagnosing HCC. As in KQ 1, potential modifiers of measures of test performance will be evaluated, including the reference standards used (e.g., explanted liver samples, histological diagnosis, or clinical and imaging followup), patient and tumor-level characteristics (e.g., body mass index, number of lesions, tumor diameter, or cause of liver disease), or other factors (e.g., technical aspects of the imaging techniques, biomarker levels, test operator or interpreter skill, setting).
- Intermediate outcomes include:
  - Effects on diagnostic thinking.
- Effects on clinical decisionmaking.
  - Clinical and patient centered outcomes include:
  - Overall mortality or survival.
  - Recurrence of HCC, including rates of seeding by fine-needle aspiration
  - Quality of life as measured with scales such as the Short-Form Health Survey (SF–36) or EuroQol 5D (EQ–5™) or as defined by the primary studies.
  - Psychosocial effects of diagnostic testing on patients, patients' caregivers, and other family members, as measured by self-reported questionnaire instruments.
  - Resource utilization and patient burden (e.g., costs associated with the imaging procedure, access to the imaging facility, the number of imaging procedures and other procedures conducted).

Key Question 3
- Diagnostic outcomes include:
  - Measures for stage-specific accuracy of imaging (e.g., Obuchowski method for calculating the area under the receiver operating curve, stage reclassification rates).
- Intermediate outcomes include:
  - Effects on diagnostic thinking.
  - Effects on clinical decisionmaking.
- Clinical and patient-centered outcomes include:
  - Overall mortality or survival.
  - Recurrence of HCC, including rates of seeding by fine-needle aspiration
  - Quality of life as measured with scales such as the Short-Form Health Survey (SF–36) or EuroQol 5D (EQ–5™) or as defined in the primary studies.
  - Psychosocial effects of diagnostic testing on patients, patients' caregivers, and other family members as measured by self-reported questionnaire instruments.
  - Resource utilization and patient burden (e.g., costs associated with the imaging procedure, access to the imaging facility, the number of imaging procedures and additional procedures conducted).

Key Questions 1d, 2d, and 3d (Adverse Events or Harms)

- Adverse effects or harms associated with the imaging techniques (e.g., test-related anxiety, adverse events secondary to venipuncture, contrast allergy, exposure to radiation).
- Adverse effects or harms associated with test-associated diagnostic workup (e.g., harms of biopsy or harms associated with workup of other incidental tumors discovered on imaging).

Timing

- No restrictions will be placed on timing.
- For studies of comparative effectiveness, duration of followup, timing of interventions, and frequency of interventions will be recorded.

Settings

- All relevant care settings (e.g., primary and secondary care).

Dated: August 6, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013–19714 Filed 8–13–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-13–0743]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Assessment and Monitoring of Breastfeeding-Related Maternity Care Practices in Intra-partum Care Facilities in the United States and Territories (OMB No. 0920–0743, exp. 12/31/2011)—Reinstatement with Changes—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Health professionals recommend at least 12 months of breastfeeding, and Healthy People 2020 establishes specific national breastfeeding goals. In addition to increasing overall rates, a significant public health priority in the United States (U.S.) is to reduce variation in breastfeeding rates across population subgroups. Because hospital practices strongly influence infant feeding outcomes, the health care system is one of the most important and effective settings for improving breastfeeding initiation rates.

In 2007, CDC conducted the first national survey of Maternity Practices in Infant Nutrition and Care, known as the mPINC Survey. The survey inquired about care practices and support for breastfeeding throughout the maternity stay as well as staff training and maternity care practices. Following the collection of baseline information in 2007, the mPINC survey was conducted again in 2009 and 2011.

CDC proposes to repeat the mPINC in 2013 and 2015, with changes. In previous cycles of data collection, two versions of the mPINC survey instrument were used: one for hospitals and one for birth centers. In 2013 and 2015, one instrument will be used for both hospitals and birth centers. There are no changes to survey content, other than the minor changes needed to produce a single streamlined instrument for all facilities. There is no change to the estimated burden per response (30 minutes). Similarly, in 2013 and 2015 screening for eligible facilities will be conducted with a single screening instrument.

Facilities will identified by using information obtained through the American Association of Birth Centers (AABC) and the American Hospital Association (AHA) Annual Survey of Hospitals. Facilities that will be invited to participate in the survey include those that participated in previous iterations and those that were invited but did not participate in the previous iterations, as well as those that have become eligible since the most recent mPINC survey. All birth centers and hospitals with ≥1 registered maternity bed will be screened for eligibility via a brief phone call to assess their eligibility, identify additional locations, and identify the appropriate point of contact.

As with the initial surveys, a major goal of the 2013 and 2015 follow-up surveys is to be fully responsive to facilities' needs for information and technical assistance. CDC will provide direct feedback to respondents in a customized benchmark report of their results and identify and document progress since 2007 on their quality improvement efforts. CDC will use information from the mPINC surveys to identify, document, and share information related to incremental changes in practices and care processes over time at the hospital, state, and national levels. Data will be also used by researchers to better understand the relationships between hospital characteristics, maternity-care practices, state level factors, and breastfeeding initiation and continuation rates.

OMB approval is requested for three years. On an annualized basis, CDC estimates initial contact with 2,570 facilities that will complete Part A of the Screening Telephone Call, and 2,200 respondents that will also complete Part B of the Screening Telephone Call. CDC estimates receipt of completed surveys from 1,825 facilities.

Participation in the survey is voluntary, and responses may be submitted by mail or through a Web-based system. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,103.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name		Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Maternity facility	Screening telephone call script	Part A	2,570	1	1/60
		Part B	2,200	1	4/60
	mPINC Facility Survey		1,825	1	30/60