EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Semi-structured interview	9	9	60/60	81
Training participant questionnaire	240	10	20/60	800
Total	249	NA	NA	881

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Semi-structured interview	9	81	$44.18	$3,579
Training participant questionnaire	240	800	44.18	35,344
Total	249	881	NA	38,923

* Based upon the mean of the average wages for all health professionals (29–000) for the training participant questionnaire and for executives, administrators, and managers for the organizational leader questionnaire presented in the National Compensation Survey: Occupational Wages in the United States, May, 2012, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#37-0000*.

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, 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 16, 2013.

Carolyn M. Clancy,

Director.

[FR Doc. 2013–20826 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Imaging Tests for the Diagnosis and Staging of Pancreatic Adenocarcinoma

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 tests for the diagnosis and staging of pancreatic adenocarcinoma. Scientific information is being solicited to inform our review of *Imaging Tests for the Diagnosis and Staging of Pancreatic Adenocarcinoma,* 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 tests for the diagnosis and staging of pancreatic adenocarcinoma 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 26, 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, P.O. 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 Tests for the Diagnosis and Staging of Pancreatic Adenocarcinoma.*

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 Tests for the Diagnosis and Staging of Pancreatic Adenocarcinoma,* 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=1620.

This notice is to notify the public that the EHC program would find the following information on *imaging tests for the diagnosis and staging of pancreatic adenocarcinoma* 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=1620.*

The Key Questions

Question 1

What is the comparative effectiveness of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) for diagnosis of pancreatic adenocarcinoma in adults with suspicious symptoms?

a. What is the accuracy of each imaging technique for diagnosis and assessment of resectability?

b. What is the comparative accuracy of the different imaging techniques for diagnosis and assessment of resectability?

c. What is the comparative diagnostic accuracy of using a single imaging technique versus using multiple imaging techniques?

d. How is test experience (e.g., operative experience, assessor experience, center's annual volume) related to comparative diagnostic accuracy of the different imaging strategies?

e. How are patient factors and tumor characteristics related to the comparative diagnostic accuracy of the different imaging strategies?

f. What is the comparative clinical management after the different imaging strategies when used for diagnosis?

What is the comparative impact of the different imaging strategies on long-term survival and quality of life when used for diagnosis?

Question 2

What is the comparative effectiveness of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) for *staging* of pancreatic adenocarcinoma among adults with a diagnosis of pancreatic adenocarcinoma?

a. What is the staging accuracy of each imaging technique (for tumor size, lymph node status, vessel involvement, metastases, stage [I–IV], and resectability)?

b. What is the comparative staging accuracy among the different imaging techniques?

c. What is the comparative staging accuracy of using a single imaging technique versus using multiple imaging techniques?

d. How is test experience (e.g., operative experience, assessor experience, center's annual volume) related to comparative staging accuracy of the different imaging strategies?

e. How are patient factors and tumor characteristics related to the comparative staging accuracy of the different imaging strategies?

f. What is the comparative clinical management of the different imaging strategies when used for staging?

What is the comparative impact of the different imaging strategies on long-term survival and quality of life when used for staging?

Question 3

What are the rates of harms of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) when used to diagnose and/or stage pancreatic adenocarcinoma?

a. How are patient factors related to the harms of different imaging techniques?

What are patient perspectives on the tolerance of different imaging techniques and the balance of benefits and harms of different imaging techniques?

Question 4

What is the comparative screening accuracy of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) in high-risk asymptomatic adults (i.e., those at genetic or familial risk of pancreatic adenocarcinoma)?

Dated: August 19, 2013.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2013–20849 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0520]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of