Comparators

- Any direct comparisons of the imaging tests of interest
- Any direct comparisons of variations of any of the imaging tests of interest (e.g., diffusion-weighted MRI vs. T2-weighted MRI)

Comparators thought to be of particular clinical interest are listed below:

- For colon cancer: A contrast-enhanced CT of the chest, abdomen, and pelvis versus whole-body PET/CT versus a contrast-enhanced MRI of the chest, abdomen, and pelvis
- For rectal cancer: A contrast-enhanced CT of the abdomen and pelvis versus an MRI of the abdomen and pelvis
- For rectal cancer: Endoscopic ultrasound versus MRI
- For suspected liver metastasis: CT scan versus MRI or PET/CT of the abdomen
- For suspected widespread metastasis, CT of the chest, abdomen, and pelvis versus whole-body PET/CT or contrast-enhanced MRI of the chest, abdomen, and pelvis

We note that this list is based on a preliminary literature search and discussions with a limited number of clinicians and the Technical Expert Panel (TEP). Thus, we do not anticipate that the listed items cover all of the comparisons of interest. We expect that additional comparisons will be identified during the literature review.

Outcomes

- Test performance outcomes.
  - Test performance (e.g., sensitivity, specificity, understaging, and overstaging) against a reference standard test (pathological examination, intraoperative findings, clinical followup).
- Intermediate outcomes.
  - Stage reclassification.
  - Changes in therapeutic management.
- Clinical outcomes.
  - Overall mortality.
  - Colorectal cancer–specific mortality.
  - Quality of life and anxiety.
  - Need for additional staging tests, including invasive procedures.
  - Need for additional treatment, including surgery, radiotherapy, or chemotherapy.
  - Resource utilization related to testing and treatment (when reported in the included studies).
  - Adverse effects and harms.
  - Harms of testing per se (e.g., radiation exposure).
  - Harms from test-directed treatments (e.g., overtreatment, undertreatment).

Timing

- Primary staging.
- Interim restaging.
- Duration of followup will vary by outcome (e.g., from no followup for test performance measurements to many years for mortality).

Setting

- Any setting will be considered.

Dated: July 11, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013–17176 Filed 7–17–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0307]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 (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

The Gonococcal Isolate Surveillance Project (GISP), OMB No. 0920–0307 exp. 12/31/2013)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain Office of Budget and Management (OMB) approval to revise the data collection for the Gonococcal Isolate Surveillance Project (GISP) (OMB No. 0920–0307, expires 12/31/2013). CDC seeks a three-year approval to conduct the GISP project. Revisions to this ICR consist of removing 4 variables from Form 1: Demographic/Clinical Data. The four variables to be removed are: (1) Total monthly number of gonococcal infections; (2) date of birth of the patient; (3) zip code of the patient; and (4) reason for visit. The variables to be removed have not proven useful at the federal level and removal of the variables will not increase or decrease the burden. The objectives of GISP are: (1) To monitor trends in antimicrobial susceptibility of strains of *Neisseria gonorrhoeae* in the United States and (2) to characterize resistant isolates. Surveillance of *N. gonorrhoeae* antimicrobial resistance is important because: (1) Nearly all gonococcal infections are treated empirically and susceptibility testing data are not routinely available in clinical practice; (2) *N. gonorrhoeae* has consistently demonstrated the ability to develop resistance to the antimicrobials used for treatment; (3) effective treatment of gonorrhea is a critical component of gonorrhea control and prevention, and (4) untreated or inadequately treated gonorrhea can cause serious reproductive health complications. GISP is the only source in the United States of critical national, regional, and site-specific gonococcal antimicrobial resistance data. GISP provides information to support informed and scientifically-based treatment recommendations.

GISP was established in 1986 as a voluntary surveillance project and now involves 5 regional laboratories and 30 publicly funded sexually transmitted disease (STD) clinics around the country. The STD clinics submit up to 25 gonococcal specimens (or isolates) per month to the regional laboratories, which measure susceptibility of the isolates to multiple antimicrobial drugs. Limited demographic and clinical information corresponding to the isolates (and that do not allow identification of the patient) are submitted directly by the clinics to CDC.

During 1986–2012, GISP has demonstrated the ability to effectively achieve its objectives. The emergence of resistance in the United States to penicillin, tetracyclines, and fluoroquinolones among *N. gonorrhoeae* isolates was identified through GISP. Increased prevalence of fluoroquinolone-resistant *N. gonorrhoeae* (QRNG), as documented by GISP data, prompted CDC to update treatment recommendations for gonorrhea in CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006 and to release an MMWR article stating that CDC no longer recommended fluoroquinolones for treatment of gonococcal infections. Recently, GISP isolates demonstrated increasing minimum inhibitory concentrations of cefixime, which can be an early warning of impending

resistance. This worrisome trend prompted CDC to again update treatment recommendations and no longer recommend the use of cefixime as first-line treatment for gonococcal infections.

Under the GISP protocol, each of the 30 clinics submit an average of 20 isolates per clinic per month (i.e., 240 times per year) recorded on Form 1: Demographic/Clinical Data. The estimated time for clinical personnel to abstract data for Form 1: Demographic/Clinical Data is 11 minutes per response.

Each of the five Regional laboratories receives and processes approximately 20 isolates from each referring clinic per month (i.e., 121 isolates per regional laboratory per month [based on 2011 specimen volume]) using Form 2: Antimicrobial Susceptibility Testing. For Form 2: Antimicrobial Susceptibility Testing, the annual frequency of responses per respondent is 1,452 (121 isolates × 12 months). Based on previous laboratory experience, the estimated burden of completing Form 2 for each participating laboratory is 1 hour per response, which includes the time required for laboratory processing of the patient's isolate, gathering and maintaining the data needed, and completing and reviewing the collection of information. For Form 3: Control Strain Susceptibility Testing, a ''response'' is defined as the processing and recording of Regional laboratory data for a set of seven control strains. It takes approximately 12 minutes to process and record the Regional laboratory data on Form 3 for one set of seven control strains, of which there are 4 sets. The number of responses per respondent is 48 (4 sets × 12 months). There are no additional costs to respondents. The total estimated annual burden hours are 8,628.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Clinic	Demographic Clinical Data Form 1	30	240	11/60
Laboratory	Antimicrobial Susceptibility Testing Form 2	5	1,452	1
	Control Strain Susceptibility Testing Form 3	5	48	12/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10062, CMS–10146, CMS–10191, CMS–10308, CMS–R–43 and CMS–10453]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 19, 2013:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, or Email: *OIRA_submission@omb.eop.gov* .

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk