Image-Assisted Cytology Workload Assessment and Measure

Request for Approval of New Data Collection

Supporting Statement A

August 23, 2013

Contact:

MariBeth C. Gagnon, M.S.
Cytotechnologist
Division of Laboratory Science and Standards
Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention
1600 Clifton Rd.
MS F-11
Atlanta, Georgia 30333
Phone: 404.498.2745
Fax: 404.498.2740
Email: mgagnon@cdc.gov

Image-Assisted Cytology Workload Assessment and Measure

Request for Approval of New Data Collection

Supporting Statement A

Attachments

Image-Assisted Cytology Workload Practice Survey

Request for Approval of New Data Collection

Supporting Statement A

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Information Collection Request (ICR) is new and needs approval for 12 months. The results of this cytology workload practice survey may be used by the Department of Health and Human Service (HHS) agencies responsible for the Clinical Laboratory Improvement Amendments (CLIA) program to determine appropriate gynecologic cytology screening workload maximums using semi-automated devices. The CLIA regulations have provisions for a workload maximum for manual screening and instruct laboratories to follow the manufacturer's instructions when using a semi-automated screening device. Standards for counting need to be developed for consistency between the different devices. There is currently no data to support the development of standards. This survey will provide information to help HHS set the standards.

Background, Need and Circumstances

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) directed the Secretary of Health and Human Services to establish the maximum number of cytology slides that any individual may screen in a 24 hour period; to establish certain quality assurance standards; to set personnel standards; and to provide for periodic proficiency testing of cytotechnologists and pathologists involved in screening and interpreting cytological preparations. The regulations implementing CLIA, published in the *Federal Register* of February 28, 1992, established that the maximum number of slides examined by an individual in each 24 hour period was not to exceed 100 slides and could not be examined in less than an eight hour day. The regulation further established that the technical supervisor is required to evaluate the performance of cytotechnologists at least every six months and determine their individual maximum daily workload limit. (Attachment A contains the appropriate section of the CLIA regulations.)

In 1992, when the regulation was published, all Pap slides were conventional "Pap smears." In a conventional Pap smear, samples are smeared directly onto a glass microscope slide after collection. The cells are often obscured by blood or the smear may be too thick and contain contaminating artifacts. Today, almost all Pap tests in the U.S. are collected with a liquid-based method. Instead of "smearing" cervical cells directly onto a glass microscope slide, the cells are sent to the laboratory in a liquid preservative and processed by an automated processor. This processor disperses a uniform thickness representative sample on the slide that is free of obscuring blood, mucus, and non-diagnostic debris in a circle that covers less than one half of the slide.

The Federal Advisory Committee for CLIA, the Clinical Laboratory Improvement Advisory Committee (CLIAC) has discussed cytology workload on numerous occasions from 1996 until present. The first workgroup was convened in July 1999 to provide input on how to determine workload for liquid-based Pap slides. The workgroup suggested it would be impossible to select one number that would be appropriate for all technology since automated and semi-automated screening devices were in development and approval by the Food and Drug Administration (FDA) might occur in the near future. In 2003, the CLIA requirements were amended to require the manufacturer of a semi-automated screening device to include a maximum workload number in the product insert, rather than set a number in the CLIA regulations.

The same year the amended regulations were made final, the first semi-automated device was approved which further reduced the area of screening by the cytotechnologist by using an automated review microscope to present the cytotechnologist with a set number of fields of view (FOV). This further complicated workload counting since it should take less time to review the FOVS than it would take to manually review the entire circle of the liquid-based preparation. Currently, two systems are FDA-approved, the Hologic ThinPrep® Imaging System and Becton Dickinson's Focal Point ™ Guided Screening System. The product insert for both devices includes a method of counting slides where slides screened on the automated review microscope will be counted as half (0.5) and a full manual review of the entire circle will be counted as one (1) slide.

Centers for Medicare & Medicaid Services (CMS) and FDA conducted an investigation into problems reported by surveyors of cytology laboratories regarding the two FDA-approved semi-automated screening devices. The investigation led to a different method for calculation of workload than the methods reported in the product inserts. This information was presented at the September 2010 CLIAC meeting[1] and FDA issued an alert - *How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices*. In this alert, it stated laboratories should have a clear standard operation procedure documenting the method of workload counting and explaining how the Technical Supervisor should establish workload limits for each individual. Also, the alert clarified how workload should be calculated when using either the Hologic's ThinPrep®[2] Imaging System or Becton Dickinson's Focal Point™ Guided Screening System[3]:

- All slides with full manual review (FMR) count as 1 slide (as mandated by CLIA's requirements for manual screening.
- All slides with only FOV review count as 0.5 or ½ slide
- Then, slides with both FOV and FMR count as 1.5 or 1 ½ slides
- Use these values to count workload, which should not exceed the CLIA maximum limit of 100 slides in no less than an 8-hour day.

On August 29, 2011 the American Society of Cytopathology's (ASC) Executive Board approved an ASC task force recommendation that the average laboratory cytotechnologist productivity should not exceed 70 slides and that an individual's screening time should not exceed seven (7) hours in a 24 hour period. This recommendation was presented at the ASC 2011[4] annual meeting and was endorsed unanimously by the Cytology Education and Technology Consortium member organizations: American Society for Clinical Pathology, American Society for Cytotechnology, American Society of Cytopathology, and Papanicolaou Society of Cytopathology. The College of

[1] **September 2010 CLIAC Summary, see section on** Workload Recording for Semi-automated Cytology Screening Devices (FDA) under Cytology Proficiency Testing, http://wwwn.cdc.gov/cliac/cliac0910.aspx

[2] **Thin Prep Imaging product insert,** http://www.thinprep.com/pdfs/thinprep_package_insert.pdf

[3] BD FocalPoint™ GS Imaging System Product Insert, http://www.bd.com/tripath/downloads/msds_pi/focalpoint/focalpoint_gs_pi.pdf

[4] ASC's Workload Recommendation for Automated Pap Test Screening. http://www.cytopathology.org/website/download.asp?id=6429

American Pathologists also acknowledged that the current workload limits for image assisted screening devices may be set too high for the average cytotechnologist, but that further study was needed to define best practices for semi-automated gynecologic workload limits.

The ASC Taskforce recommendation was presented at the February 2012 CLIAC[5] meeting along with presentations describing workload studies and use of the workload limit as a target. The committee issued a recommendation that CLIAC supports the use of data from operational studies, such as those presented to CLIAC, to determine if the maximum workload limit using semi-automated screening instruments is appropriate and to discourage the use of regulatory maximum workload limits as productivity targets. CLIAC recommended that standardized criteria be developed for use in determining workload limits for each individual performing screening.

Due to ongoing concerns regarding the appropriateness of the regulatory 100 slide maximum workload limit and lack of a standardized method for counting slides using the semi-automated screening devices, a study is needed to directly assess actual practice. The study needs to include an evaluation of laboratory practices related to setting individual workload limits and time and motion studies to determine the actual time spent screening slides. The time and motion studies need to also assess other factors, such as time of day, length of time spent screening, and an evaluation of the accuracy of diagnosis.

1.1 Privacy Impact Assessment

Overview of the Data Collection System

A notice that the survey is being conducted will be mailed (electronically and via paper by a contractor) to all cytology laboratories listed in the CLIA database as having a certificate in cytology. The notice will instruct laboratories how to complete the *Image-Assisted Cytology Workload Practices Survey* (See Attachment C) and how individual cytotechnologists may complete the *Image-Assisted Cytology Workload Assessment Survey* (See Attachment D). The data will be collected by a contractor that has on-site access to cytology laboratories, as a CMS approved accrediting agency, CMS approved proficiency testing program, or has a formal arrangement with CMS to conduct on-site laboratory inspections or surveys. The information will be collected via a paper and pencil survey. Once the data has been collected, it will be transferred to and stored on the contractor's password protected database. The data will not be accessible by non-contractor personnel.

Describe the information to be collected

The survey questions will include multiple choice questions relating to laboratory workload practices in cytology. The survey will also include questions on individual workload practices. The results will be used to guide the HHS in setting a maximum workload number identified in CLIA. No sensitive information is requested at any point in the survey.

During the data collection process, respondent information will be kept secure. No Personally Identifiable Information (PII)/IIF is being collected from respondents. The survey does not ask for any information related to individuals. The survey asks for information regarding laboratory practices. Survey responses will be submitted via paper and pencil method, and neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents. No laboratory identifiers will be retained in the final survey data set.

---

[5] February 2012 CLIAC Summary, see section on **Semi-Automated Cytology Workload,** http://wwwn.cdc.gov/cliac/cliac0212.aspx

See Information Collection Request Worksheet Part 1 as Attachment J or Information Collection Details Worksheet Part 2 a and b as Attachments K and L for additional information.

2. Purpose and Use of the Information Collection

The information collected in this survey will be used only once to provide an assessment of current practices cytology laboratories use to determine individual workload maximums. This information will be used by our contractor and the Centers for Disease Control and Prevention (CDC) to select a stratified sample of individuals to participate in a time measure study to identify the range of time cytotechnologist spends screening Pap tests. The information will also be published by CDC and the contractor in a peer-reviewed journal.

2.1 Privacy Impact Assessment

Description of How the Information Will be Shared and for What Purpose
The information will be shared with HHS agencies responsible for the CLIA program to determine appropriate gynecologic cytology screening workload maximums using image-assisted devices. In addition the information will be published in a peer-reviewed journal. In both instances the data will only be reported in aggregate.

Statement detailing the Impact the Proposed Collection Will have on the Respondent's Privacy
No individually identifiable information will be collected.

3. Use of improved Information Technology and Burden Reduction

The information will be collected using a paper and pencil survey. The survey will collect only the minimum information necessary for the project.

4. Efforts to Identify Duplication and Use of Similar Information

We have not found similar data reported through a search of the literature and an environmental scan of the internet. We consulted subject matter experts to discuss the collection of this information and none of the members knew of a similar collection of data. The experts provided suggested topics, reviewed the questions and provided information on how this data could be collected from laboratories by the least intrusive method.

5. Impact on Small Businesses or Other Small Entities

The majority of medical laboratories, including cytology laboratories are small entities, either by virtue of being nonprofit organizations or by meeting the Small Business Administration definition of a small business by having revenues of less than $13.5 million in any 1 year. We believe at least 83 percent of medical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet updated June 24, 2010 (http://www.aha.org/aha/resource-center/Statistics-and-Studies/Fast_Facts_Nov_11_2009.pdf). The questions included in this survey have been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

The request is for a one time data collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-day Notice was published in Vol. 78, No. 60 on Thursday, March 28, 2013, pages 18983 - 18985. (See Attachment B) There were two public comments and one request for an extension received. (See Attachment E) The comments described the agency's need for this information to determine reasonable workloads that are balanced with accurate Pap slide interpretation, which is more critical with longer intervals between testing. Comments that addressed burden stated that the burden could be minimized with automated reporting and by using expert consultants to minimize the number of questions that will require responses. CDC convened a group of experts prior to developing the questions and is soliciting a contractor to implement the survey. The contractor must have on-site access to cytology laboratories, as a CMS approved accrediting agency, CMS approved proficiency testing program, or has a formal arrangement with CMS to conduct on-site laboratory inspections or surveys. This contract is scheduled for award in September 2013.

We consulted with our HHS colleagues at CMS, FDA and cytology experts outside of the agency on the availability of the data, clarity of the instructions and record keeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported. The meeting was held in Silver Springs, Maryland at the FDA facility in August of 2012. (See Attachment F) The consultants have reviewed and commented on the questions contained in the survey.

9. Explanation of Any Payments or Gift to Respondents

No incentive or gift will be provided for participation.

10. Assurance of Confidentiality Provided to Respondents

This submission has also been reviewed by the CIO and it was determined that the Privacy Act does not apply. During the data collection process, respondent information will be kept secure. No identifiable information will be collected from respondents. (See Attachment G)

The Laboratory Science Policy and Practice Program office has determined that the data collection is not research involving human subjects and that IRB approval is not required. (See Attachment H)

11. Justification for Sensitive Questions

No sensitive data will be collected.

12. Estimates of Annualized Burden and Costs

Each laboratory will receive an advance request to participate in the survey from a CDC contractor that has been selected to collect the survey data and conduct the time measure study. Respondents will be from the 1,245 cytology laboratories in the Unites States. Since a response to this survey is voluntary we would expect an 80% response rate or approximately 996 laboratories. Responses would be submitted in written format. The estimated burden per response is one half (0.5) hour. The data will be a one-time collection.

CDC expects that information collection will begin in November 2013 and end February 2014.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Cytology Supervisor	Cytology Laboratory Workload Practices	996	1	30/60	498
Cytotechnologists	Cytology Workload Assessment	4,581	1	30/60	2290.5
Total					2788.5

Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. of Responses per respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)	Hourly wage rate	Total Respondent Costs
Cytology Supervisor	Cytology Laboratory Workload Practices	996	1	30/60	498	$40.52	$20,178.96
Cytotechnologists	Cytology Workload Assessment	4,581	1	30/60	2290.5	$29.44	$67,432.32
Total							$87,611.28

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
There are no additional costs to respondents other than their time estimated above.

14. **Annualized Cost to the Government**

A contract will be used to collect and analyze the data. The cost will be incurred as a single task under a 2 year contract award. The costs for this task are as follows:

Item	Quantity	Price	Total
Delivery of survey –mailed	1	$15,000.00	$15,000.00
Project manager	520 hours	$40.52	$21,070.40
Survey manager	520 hours	$35.33	$18,371.60
Technical Specialist	1040 hours	$36.54	$38,001.60
Cytotechnologist(s)	520 hours	$29.44	$15,308.80
Cytopathologist(s)	520 hours	$80.00	$41,600.00
Fringe for Task 1@30%			$ 40,305.72
Total			$189658.12

15. **Explanation of Program Changes or Adjustments**

This is a new data collection. No program changes or adjustments are anticipated.

16. **Plans for Tabulation and Publication Time Schedule**

Table A.16.1 Project Time Schedule

Activity	Time Schedule
Protocol for survey distribution	60 days after OMB approval
Surveys distributed	60 days after OMB approval
Database for collection designed and operational	90 days after OMB approval
Data from survey collected	120 days after OMB approval
Data from survey analyzed	180 days after OMB approval
Protocol for validation of survey data	180 days after OMB approval
Complete validations of survey data	270 days after OMB approval
Provide CDC with copy of data	360 days after OMB approval
Draft publishable manuscript with CDC	360 days after OMB approval

17. **Reason(s) for Display of OMB Expiration Date Is Inappropriate**

The display of the OMB expiration date is not inappropriate.

18. **Exceptions to Certification for Paperwork Reduction Act Submissions**

There are not exceptions to the certification.