Attachment E: Comments and Responses to 60-day Federal register Notice

Comments and Responses to the 60 Day FRN

1) Comment:

(a) The workload information gained from this survey has the potential for practical utility in providing a snapshot of current practice IF appropriate laboratories respond.

(c) The quality and utility of data would be much greater is responses are required from all laboratory types; hospital, private, large, small

d) The survey should be as short as possible to encourage participation and enhance accuracy, minimize number of *estimated* responses. What is the essential question we are asking?

Response:

Thanks for all of the comments; we agree that the survey should be short and to the point. The purpose of the survey is to collect information on individual workload range stratified by the type and size of the laboratory where they work.

2) Comment:

Response to request for public comment and recommendations regarding the proposed data collection on cytology workload assessment and measures.

(Proposed Project: Cytology Workload Assessment and Measure--New--Office of Surveillance, Epidemiology and Laboratory (OSELS), Centers for Disease Control and Prevention (CDC). [FR Doc. 2013-07233 Filed 3-27-13]

I support the proposal to collect data using a survey to assess measures relating to establishing gynecologic cytology workload.

In direct response to your questions:

1. The proposed data collection is necessary for agency performance.

Pap tests have changed significantly since the introduction of CLIA 88. A cytotechnologist no longer screens a conventional Pap smear hoping to locate an abnormal cell. And Pap tests are no longer an annual event, allowing for multiple opportunities to detect the abnormal cell in anyone woman. Image assisted screening (automated screening) of Pap tests shifts the burden of work for the cytotechnologist from locating abnormal cells to recognizing and interpreting cellular changes that are detected by the instrument. Newly implemented screening guidelines increase screening intervals to 3-5 years, with fewer opportunities to screen women, there is an increased need for greater accuracy. Accuracy of a single Pap test review takes precedence over multiple opportunities for testing during an individual's screening lifetime.

- As the penetration of HPV vaccine increases, there will be less cytologist exposure to abnormal lesions and greater importance of detecting rare abnormal cells on a single preparation. Recent publications from Elsheikh et al and others (see references below) suggest that automated work load limits for Pap tests recommended by manufacturers are excessive. The scientific evidence suggests that more emphasis should be placed on quality assurance, thorough screening, and accurate interpretation to avoid human and instrument errors. A survey and time study required for these activities would allow the agency to make scientifically valid changes in gynecologic cytology workload values.
- Alternative quality assurance measures may be necessary when using image assisted screening. The currently required 10% review of negative Pap tests is statistically worthless, given the low prevalence of cervical cancer. A second human screening (rapid re-screening) may be a viable option for quality assurance for image assisted screening, and should not be considered as a "full screen" (full manual review) as currently calculated.

- Additionally, it may be more appropriate to establish workload limits as a laboratory average, shifting emphasis from individual performance as indicated by EI Sheik et all. This shift from individual to laboratory standards will require studies in operationalizing such methods.
- Current Federal Register regulations on workload include *both* gynecologic (Pap tests) and non-gynecologic (diagnostic cytology) slides. The process and methods of interpretation for Pap tests and nongynecologic cytology are disparate. All nongynecologic specimens are always reviewed and reported by a pathologist; most Pap tests do not have pathologist review. It may be more reasonable to establish workload guidelines for *Pap tests only*, since current trends in cytology emphasize diagnosis rather than screening of nongynecologic tests, with the addition of molecular and other ancillary testing. The increase in nongynecologic specimen volume and relative decrease in Pap test volume has reversed the ratio of gynecologic and nongynecologic specimens. Nongynecologic specimens have gained increased importance in personalized cancer medicine. Nongynecologic tests now include processes to detect distinct markers that provide information on response to therapy and prognosis. Cytotechnologists are critical to this process and have been increasingly employed to provide specimen adequacy for fine needle aspiration, initial screening and interpretation of nongynecologic specimens, interpretation of fluorescent in-situ hybridization tests, and other activities.

2. The data has practical utility.
   - The data collected will provide laboratories with standardized methods and best practices recommendations for collection and recording workload data for cytotechnologists.
   - The data could be used to modify current regulations.
   - The Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the Cytotechnology Program Review Committee are in the process of redefining entry level competencies for cytotechnologists. These changes will shift the focus of work for cytotechnologists from screening Pap tests to other activities that reflect current and evolving changes in field of healthcare.
3. How accurate is the CDC's estimate of burden for collecting data?
   Data collection through surveys is not unduly burdensome for most laboratories, provided the survey is relatively short, clear and focused. National organizations closely involved in cytology practice, including the College of American Pathologists and the American Society of Cytopathology, could collaborate to produce an appropriate workload survey that would reach a wide audience.
4. The quality, utility and clarity of the information being collected can be enhanced.
   - Any timed study of cytology workload must include measurements of accuracy and quality. It would be inappropriate to monitor only the time that it takes for current practitioners to screen and interpret cytology slides without accounting for the outcomes data. There should be robust accountability for accuracy of interpretation and analysis of impact on patient care for inaccurate interpretations.
   - Time studies must include non-screening activities involved in Pap testing and cytology test interpretation, including collecting historical patient information, reviewing prior specimens, reviewing ancillary studies, and performing quality assurance activities.
5. The burden of collecting the information can be minimized.
   - Wherever possible, information collection should be automated for ease of compilation and interpretation. Time studies should include the activities of cytotechnologists from a wide variety of practice settings in order to represent the cytopathology community as a whole.
   - Time studies should be performed over the course of a workday, not prorated from an hourly rate.
   - Time studies may require prospective data collection on patient outcomes.

- Time studies should be scientifically valid and peer-reviewed by professionals practicing cytopathology.

I appreciate the opportunity to respond publically to this call for data and to provide input on the importance of this endeavor.

REFERENCES:

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3) Elsheikh TM, Kirkpatrick JL, Fischer D, Herbert KD, Renshaw AA. Does the time of day or weekday affect screening accuracy? a pilot correlation study with cytotechnologist workload and abnormal rate detection using the ThinPrep Imaging System. *Cancer Cytopathol. 2010;118(1):41-46.*
4) Frable WJ, Pedigo MA, Powers CN, Yarrell C, Ortiz B, Clark ME, Ebron T. Rapid prescreen of cervical liquid-based cytology preparations: results of a study in an academic medical center. *Diagn Cytopathol.* 2012 Aug;40(8):691-697.
5) Renshaw AA, Elsheikh TM. Predicting screening sensitivity from workload in gynecologic cytology: a review. *Diagn Cytopathol.* 2011 ;39(11):832-836.
6) Renshaw AA, Elsheikh TM. Sensitivity and workload for manual and automated gynecologic screening: best current estimates. *Diagn Cytopathol.* 2011 ;39(9):647-650.
7) Elsheikh TM, Austin RM, Chhieng DF, Miller FS, Moriarty AT, Renshaw AA. American Society of Cytopathology workload recommendations for automated pap test screening: Developed by the productivity and quality assurance in the era of automated screening task force. *Diagn Cytopathol.* 2012 Feb 20. [Epub ahead of print]
8) Renshaw AA, Elsheikh TM. Sensitivity and workload for manual and automated gynecologic screening: best current estimates. *Diagn Cytopathol.* 2011 ;39(9):647-650

Response:

Thank you for commenting on our survey for cytology workload assessment and measure. We agree with all the comments provided. We sought advice through expert consultation on the survey and discussed how to address all of the concepts reported in the comment. The expert consultants included Dr. Elsheikh (referenced in her comment).

3) Request for an extension:

The College of American Pathologists would like to request an extension to provide comments to the Proposed Project: Cytology Workload Assessment and Measure--New--Office of Surveillance, Epidemiology and Laboratory (OSELS), Centers for Disease Control and Prevention (CDC). [FR Doc. 2013-07233 Filed 3-27-13].

The deadline is Monday, May 27. We request an extension of two weeks. Please feel free to contact me at your convenience. I have also left a voice mail message to this same effect.

Thank you for considering this request.

Response:

Thank you for your interest in this project. Unfortunately, the 60-day comment period on the Proposed Project: Cytology Workload Assessment and Measure has ended. However, there will be another opportunity to comment on this project once the 30-day Federal Register Notice is published.