Introduction to Semi-Automated Cytology Workload

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CLIAC Meeting
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Outline

- CLIA Requirements
- Background
- Purpose for CLIAC Discussion
- Questions for CLIAC Consideration
- Introduction of Speakers
CLIA Requirements

- **Manual screening - §493.1274(d)**
  - Technical Supervisor determines the maximum workload based on the individual’s performance
  - Each individual’s workload is reassessed every 6 months
  - Maximum number should not exceed 100 slides in 8 hour day
  - Formula for calculating workload for less than an 8 hour day

- **Automated and semi-automated screening devices - §493.1274(g)**
  - Must follow the manufacturer’s instructions
Background

- **July 1999: CLIAC Workgroup** – The Impact of New Technology on Workload Limitations
  - Purpose of meeting was information gathering
  - Diane Solomon, MD; NIH was the Chair
  - WG comprised of pathologists and cytotechnologists
  - CDC, CMS, and FDA were represented
  - Presentations were made by manufacturers of semi-automated technology for gynecologic cytology
Background

- **September 1999 CLIAC Meeting**
  - CDC Update included a presentation on the July WG
  - CLIAC members provided the following comments--
    - Standards needed to be developed for manual methods, instrumentation, and associated computer hardware
    - The need for security and confidentiality related to managing computer images was also emphasized

http://www.cdc.gov/cliac/cliac0999.aspx#t5
Background

- **February 2003: Cytopathology Education and Technology Consortium (CETC)**
  - Taskforce published a document *Daily Workload Guidelines for Cytotechnologists Utilizing Automated Assisted-Screening Technologies*
    - Provided guidance to the Food and Drug Administration (FDA) and other regulatory bodies for evaluation of cytotechnologist workload limits
    - Listed data elements to be used in clinical trials for comparing manual and automated cytology screening methods

http://www.cytopathology.org
FDA Approvals

- **2003: ThinPrep® Imaging System**
  - Review of 22 Field of View (FOV) per slide
  - Maximum workload of 200 FOV slides*

- **2008: FocalPoint™ Slide Profiler**
  - Review of 10 FOV per slide
  - Maximum workload of 170 slides*

*Product insert (initial clearance) - manufacturer’s instructions for workload
Image source: Google images.
Background

- **September 2010 CLIAC Meeting**
  - CMS presentation on Cytology Survey process
  - Surveyors had identified problems with two FDA-approved cytology semi-automated screening devices
    - Both devices were found to have problems identifying unsatisfactory slides and certain types of abnormal cells
    - Laboratories were not calculating workload properly when using these screening devices.

http://www.cdc.gov/cliac/cliac0910.aspx#t5_1_2
Background

- **September 2010 CLIAC Meeting**
  - FDA presented the results of their investigation into problems reported by CMS regarding two FDA-approved semi-automated screening devices for Pap tests
  - FDA and CMS determined that the following method should be used for calculation of workload when using the semi-automated screening devices
    - Full manual review (FMR) count as 1 slide,
    - Field of view (FOV) only review count as 0.5 slide,
    - Both FMR and FOV count as 1.5 slides.
    - Formula: $1.5(# \text{ slides with both FMR and FOV}) + .5(# \text{ of slides FOV}) + 1(FMR) \leq 100$. 

October 2010 FDA issued an alert - *How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices*

- Clarified for laboratories how workload should be calculated when using current FDA-approved semi-automated gynecologic cytology screening devices
- Presented examples of different counting scenarios that a cytotechnologist may encounter

[http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm220292.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm220292.htm)
Background

- **November 2011: American Society of Cytopathology Taskforce**
  - Recommendations for Automated Pap Test Screening
    - 70 slide workload maximum
    - Endorsed unanimously by CETC organizations
      - American Society for Clinical Pathology
      - American Society for Cytotechnology
      - International Academy of Cytology
      - Papanicolaou Society of Cytopathology
    - College of American Pathologists approval pending
Purpose for CLIAC Discussion

- Inform CLIAC of the FDA revised method for counting workload for cytology semi-automated screening devices
- Ask CLIAC member to provide input on the best approach to keep laboratories informed of product labeling changes
- Consider an ASC Taskforce Recommendation to lower the workload maximum when using cytology semi-automated screening devices
Automated Cytology Workload Questions for CLIAC Consideration

1. How can HHS determine if the maximum workload limit using semi-automated screening instruments is appropriate?

2. What are the potential impacts to lowering the workload limits for screening using a semi-automated device?
Introduction of Speakers

- Tremel Faison MS, RAC, SCT(ASCP) FDA-OIVD
  - *Workload Issues for Computer-Aided Cytology Devices*
- William N. Crabtree, PhD
  University of Indiana School of Medicine
  - *A Career that has Eternal Significance*
- Tarik Elsheikh, MD
  Cleveland Clinic
  - *ASC Task Force Recommendations for Productivity and Quality Assurance in the Era of Automated Screening*
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.