Introduction to Semi-Automated Cytology Workload

MariBeth Gagnon, MS CT(ASCP)HTL
CDC/OSELS/LSPPPO/DLSS

CLIAC Meeting
February 14, 2012

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

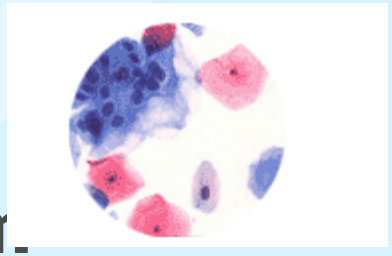
- **September 1999 CLIAC Meeting**
  - CDC Update included a presentation on the July WG
  - CLIAC members provided the following comments--
    - Standards needed to be developed for manual methods, instrumentation, and associated computer hardware
    - The need for security and confidentiality related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

http://wwwn.cdc.gov/cliac/cliac0999.aspx#t5

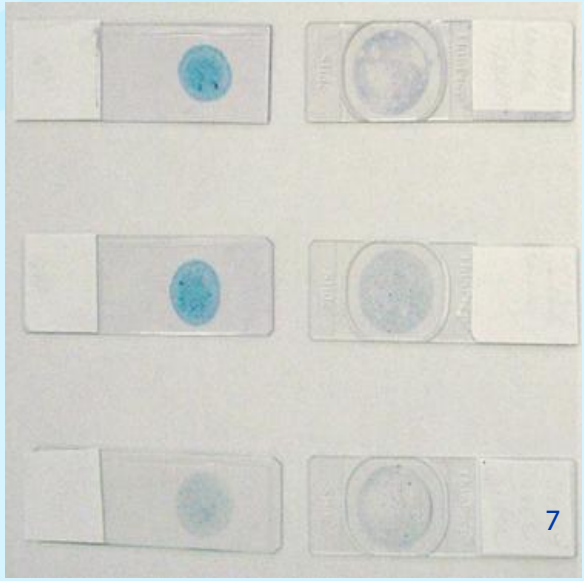
Background

- **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

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://wwwn.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(# slides with both FMR and FOV) + .5(# of slides FOV) + 1(FMR) ≤ 100.

Background

- **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

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

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Mailstop F-11, Atlanta, GA 30333
CLIA Information Line: 1-404-498-2290 TTY: 1-888-232-6348
E-mail: mgagnon@cdc.gov Web: http://wwwn.cdc.gov/cliac/default.aspx