Learning Objectives

• Discuss CLIA 88 and compliance requirements unique to the Cytopathology laboratory
• Explain the rationale behind the new/recent checklist requirements as they apply to areas in the cytology laboratory
• Describe the deficiencies most frequently cited during inspections of cytology laboratories and strategies to avoid these
• Apply strategies for preparation of unannounced inspections as currently required
Introduction:

Dr. Dina Mody
Director of the Cytopathology Laboratory and Fellowship at The Methodist Hospital
Lax Laboratories
The Pap Test Misses Much Cervical Cancer Through Labs’ Errors
Cut-Rate ‘Pap Mills’ Process Slides Using Screeners With Incentives to Rush
Misplaced Sense of Security?

By Walt Bogdanich
Staff Reporter of The Wall Street Journal
CLIA 88

- Cytology considered a high complexity test
- Sept 10, 1990
- Final Rule, Feb 1992
CLIA 88 and Cytology

- Personnel Standards
- Workload Limits
- Hierarchical Review of slides
- Rescreen functions and performance evaluations
- Proficiency Testing*
Major Regulatory Agencies

- CMS - Responsible for enforcing provisions of CLIA 88
- FDA
- OSHA
Certification and Accreditation

• Moderate and high complexity laboratories must undergo onsite surveys at least every two years.
• CMS utilizes an outcome oriented survey protocol
  – ensure quality test results
  – identifies problems that could cause actual or potential harm to patients.
Deemed Status Cytology

- AOA HFAP (Healthcare Facilities Accreditation Program)
- CAP LAP
- TJC (reciprocity with CAP as well as own lab accreditation program)
- COLA (recognized by TJC and approved by CMS approved)
- HCFA/CMS/CLIA State inspections
Cytology Lab Inspection Statistics

- AOA: 23 labs
- CAP: 2212 labs
- COLA: 45 labs
- HCFA/CMS: 798 labs
- TJC: 413 labs

Above based on self reported application data to CMS (4/23/2009)
For Today’s Talk

• Recent Updates – Dr. Henry
• Most frequent deficiencies – Dr. Henry
• Unannounced Inspections and pointers – Dr. Mody
Laboratory Accreditation: Recent Changes and New Questions

Michael Henry, MD
Cytopathology Resource Committee,
Director of Cytopathology Laboratory,
Mayo Clinic, Rochester, MN
Questions with “Major” Changes

- General Cytopathology Introduction – reminder that other checklists should be utilized for special techniques not covered in the cytology checklist (such as immunohistochemistry or molecular)
- CYP.02900 – deleted
- CYP.03300, 03333 and 04700 – modified
- CYP.03925 – modified for annual testing
- CYP.05325 – new question
Questions with “Major” Changes

• CYP.06450 (ANP 12175) – new question
• CYP.07600 – modified to meet new reporting needs
• CYP.07680 – revised
• CYP.08500 – split into three questions and modified
• CYP.09900 – revised to more stringent formaldehyde monitoring
CYP.02900 & 03000

• Are instructions distributed to physicians and paramedical personnel for proper collection, handling, transportation, and preparation of cytologic specimens?

• This question was deleted

• This issue is covered under Laboratory General
CYP.03300, 03333 and 04700

- These questions relate to preanalytic specimen (CYP.03300) or analytic slide (CYP.04700) labeling or both for pathologist or cytotechnologist attended FNAs (CYP.03333)
- CYP.03333 is a new question as of 9/27/2007 and requires unique labeling of collected or prepared FNA material.
- Additions to the notes for CYP.03300 and CYP.04700 now require 2 unique identifiers on received specimens and final prepared slides. This requirement meets Joint Commission (JC) standards.
CYP.03300, 03333 and 04700

• CYP.03300: In addition to the previous changes it is noted that:
  – Slides received in the lab or prepared on site may be labeled with a single unique identifier however, 2 identifiers are preferred.
  – There is a reference to GEN. 40491 for further details.
CYP.03925

- Are cytology stains assessed at least annually to ensure their proper storage and acceptable quality?
- Note modified to require that acceptable performance of these stains should be confirmed at least **annually** rather than periodically
CYP.05325

• New Phase 1 question
• For FNA procedures where a preliminary, intraoperative assessment of adequacy is made, is this assessment documented in the cytopathology report?
New Phase 1 Question: CYP.06450

• Is there a policy regarding the timely communication, and documentation thereof, of significant or unexpected cytopathology findings?

• Similar to AP question: ANP.12175 “Is there a policy regarding the timely communication, and documentation thereof, of significant or unexpected surgical pathology findings?”
New Phase 1 Question: CYP.06450

- **Note**
  - Consideration should be given to assuring, with reasonable effort, prompt communication of such results, by telephone, pager, or other system. There should be documentation of such special notification.
  - May also designate certain diagnoses as “critical results” for which communication should be prompt.
  - Diagnoses to be defined as “significant”, “unexpected” or “critical” if any, should be determined by the cytopathology department, in cooperation with local clinical medical staff.
CYP.07600

• Revised question and note to add:
  – Diagnostic categories of GYN cases by preparation type
    • Note changed to show that separate statistical data for conventional and liquid based preparation are now going to be required.
  – Negative cases rescreened before sign out

• These changes are secondary to a new requirement for laboratories to report statistical data for their laboratory to the CAP each year including:
  – Numbers of Unsat, LSIL, HSIL, Ca, ASC-US and ASC-H
  – Total number of negative cases rescreened and numbers of SILs or malignancies identified by rescreen

• Required beginning in 2009
• Revised to: Are there procedures to prevent cross-contamination of specimens during processing and staining?

• NOTE: Procedures must prevent cross-contamination between gynecologic and non-gynecologic specimens. Also, procedures must prevent contamination among non-gynecologic cases when highly cellular specimens are processed.

• Old question: Is there a documented policy for ensuring that non-gynecologic specimens with a high potential for cross-contamination are processed and stained separately from other specimens?
CYP.08500

• Very complicated question about documenting cytology workload
• Current (old) question asks: “Is there a documented workload policy with evidence of data recording?” with a long explanatory note covering the CLIA required aspects of cytology workload recording.
• New question is split into 3 questions to help clarify this issue especially regarding the pathologists requirements and computer assisted screening
CYP.08500, Phase 2

• Is there a documented workload policy for the manual screening of cytology slides with evidence of data recording?

• The note explains how to document workload for both the cytotechnologists and pathologists.

• Specifically mentions that pathologists must count unscreened non-gyn slides as part of their documented cytology workload.
  – Also specifies which slides do NOT count.
  – This clarifies a CLIA mandated requirement that was not well spelled out previously

• Adds a note that states these requirements are only applicable to labs subject to US Regulations and CLIA88
CYP 08550, Phase 2

• If applicable, is there a separate documented workload policy for the automated screening of cytology slides, with evidence of data recording?

• Laboratories should follow manufacturer’s instructions for workload calculations (note gives example for ThinPrep® Imager)
  – Slides undergoing full manual review fall under the CLIA requirement of 100 slides per day and workload for these should be recorded as noted in CYP.08500.
  – Separate records must be kept for each of these types of screening (manual and automated) per CLIA.
CYP.08575, Phase 2

- Is there a policy for the establishment of an individual maximum workload for the screening of cytology slides?
- Split out from the old CYP.08500.
- The note spells out the requirements for establishing maximum workload for individuals within the laboratory.
- Gives examples for QA measures which can be utilized to determine this maximum.
Questions with “Minor” Changes

- CYP.02200 & 04300 – combined
- CYP.07100 & 07200 – added reference
- CYP.07300 – changed wording
- CYP.08000, 08100, 08200 & 08300 – wording changed for labs not falling under CLIA 88
CYP.02200 & 04300

- CYP.02200 is deleted and 04300 changed to: Is there documented evidence of daily review of the technical quality of cytologic preparations?
- These questions were similar and while not exactly redundant caused some confusion.
  - CYP.02200 pertained to stains and
  - CYP.04300 to cytologic preparations.
- The note now reads:
  - The technical quality of preparations should be checked daily. This includes checking all stains for predicted staining characteristics each day of use. The quality of all types of cytologic preparations performed such as cytospins, cell blocks, liquid based automated preparations etc should also be checked.
CYP.07100 & 07200

- Is there a documented policy for protecting and preserving the integrity and retrieval of original slides in cytopathology?
- Is there a policy to ensure defined handling and documentation of the use, circulation referral, transfer and receipt of original slides to ensure availability of materials for consultation and legal proceedings?
- Added the exact CLIA 88 reference to both of these questions.
CYP.07300

- Changed the question to read: Is there documentation, including acknowledgment of receipt, when original diagnostic material is loaned to special programs such as the for the purpose of education and/or proficiency testing?
- Deleted specific reference to the CAP PAP program
- Added the CLIA 88 reference
- The changes were made to more accurately reflect the intent of CLIA 88 in reference to donation of original material for PT purposes (as opposed to duplicate slides)
• Are formaldehyde and xylene vapor concentrations maintained below the following maxima, expressed as parts per million?

• The laboratory must perform an initial formaldehyde monitoring procedure in all areas where this reagent is used. Further periodic formaldehyde monitoring is mandated at least every 6 months if results of the initial monitoring equal or exceed 0.5 ppm (8 hr time-weighted exposure, the “action level”) or at least once per year if the results exceed the short term exposure limit (STEL) 2.0 ppm (STEL).

• May discontinue monitoring if levels are below action levels
CYP.08000, 08100, 08200 & 08300

- Added the words: “or other applicable local, regional or national regulations” to all of these questions
- Example: CYP.08000 - Does the cytopathology laboratory have a general supervisor, as defined by CLIA-88 or other applicable local, regional or national regulations?
- These questions refer to either the general supervisor or the cytotechnologist and their qualifications and responsibilities.
- This change recognizes that some CAP inspected laboratories do not fall under federal CLIA 88 regulations but may have other applicable rules.
Top 10 list of most cited questions for a cytology laboratory
Number 10: CYP.00800
Deficiency % - 1.4%
Times asked: 1591 Times Cited: 22

- Question: Is there a clearly defined and documented quality management program in cytopathology?
- Note: Laboratories should consistently review activities and monitor their effectiveness in improving performance. Each laboratory should design a program that meets its needs and conforms to appropriate regulatory and accreditation standards.
Number 9: CYP.02200
Deficiency % - 1.6%
Times asked: 1591 Times Cited: 25

• Question: Is there documented evidence of daily review of the technical quality of cytologic preparations by the pathologist or supervisory-level cytotechnologist?
Number 8: CYP.05285
Deficiency % - 1.6%
Times asked: 1591 Times Cited: 25

- Is there a documented procedure for handling workload during instrument failure and/or
downtime?
- NOTE: This procedure must address: (a) final processing and resulting of any cases/specimens
that are within the instrument at the time of failure, and (b) alternative procedures to be used
during instrument downtime.
Number 7: CYP.07690
Deficiency % - 1.6%
Times asked: 1591 Times Cited: 25

• Question: Are 90% of reports on routine non-gynecologic cytology cases completed within 2 working days of receipt by the laboratory performing the evaluation?
Number 7: CYP.07690
Deficiency % - 1.6%
Times asked: 1591 Times Cited: 25

• NOTE: This question is primarily concerned with the majority of routine specimens, and applies to all laboratories. Longer reporting times may be allowed for specimens requiring special processing or staining (e.g., immunohistochemistry or other molecular analysis), or for screening (as opposed to diagnostic) specimens (for example, urines). If the laboratory has certain classes of specimens, patient types, etc., for which longer turnaround times are clinically acceptable, these must be identified, together with reasonable target reporting times, for Inspector review. Documentation may consist of continuous monitoring of data or reports by the laboratory. In periodic auditing of lieu of this documentation, the Inspector may audit sufficient reports to confirm turnaround time.
Number 6: CYP.03366  
Deficiency % - 1.8%  
Times asked: 651 Times Cited: 12

• If the pathologist performs FNA procedures, is there a documented procedure to prevent errors in the identification of the patient, the site and the procedure?

• REFERENCE:  
http://www.jointcommission.org/PatientSafety/UniversalProtocol/
Number 5: CYP.04050
Deficiency % - 1.8%
Times asked: 1591 Times Cited: 29

• Question: Are all reagents stored as recommended by the manufacturer?
• NOTE: Reagents must be stored as recommended by the manufacturer in order to prevent environmentally-induced alterations that could affect test performance. If ambient storage temperature is indicated, there must be documentation that the defined ambient temperature is maintained and corrective action is taken when tolerance limits are exceeded.
Number 4: CYP.09000
Deficiency % - 2.1%
Times asked: 1591 Times Cited: 33

• Question: Is sufficient space provided for processing cytologic material?
Question: Is there a documented policy for ensuring that non-gynecologic specimens with a high potential for cross-contamination are processed and stained separately from other specimens?

NOTE: Contamination may occur among cases when highly cellular specimens are processed. Methods to minimize this potential problem may include cytocentrifuge, filter, and monolayer preparations. Direct smears made from the sediment of highly cellular cases should be stained after the other cases, and the staining fluids must be changed or filtered between each of the highly cellular cases. One procedure to detect highly cellular specimens is to use a toluidine blue, or other rapid stain, on a wet preparation. One procedure to detect possible contamination is to insert a clean blank slide in each staining run and examine it for contaminating cells.
Number 2: CYP.08500
Deficiency % - 3.2%
Times asked: 1591 Times Cited: 51

• Question: Is there a documented workload policy with evidence of data recording?
Number 1: CYP.02500, Phase 2
Deficiency % - 5.1%
Times asked: 1591 Times Cited: 81

• Question: Is there documentation of at least annual review of all policies and procedures in the cytopathology laboratory section by the current laboratory director or designee?
NOTE: The director must ensure that the collection of policies and technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a title page or index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.
Closer Look at Inspections
Resources for Labs (to prepare for unannounced inspections)

- Laboratory Accreditation Manual
- Virtual Library of Audioconferences
- www.cap.org FAQs
- Email questions to accred@cap.org
- Phone 1-800-323-4040 ext. 6065
- Attachment A
Inspection Tips for Labs

• Request date of PAP PT as blackout date
• Notify administrators of process change
• Make a list of tasks and assign individuals to each
• Develop phone trees
• Do NOT reschedule vacations, personal time
• Identify and train back-ups for each area of lab; identify back-ups for hospital administrators as well
Inspection Tips for Labs

• Develop a process for timely retrieval of off-site records (document control system)
• Designate space for the team in the lab or elsewhere in the institution
• Direct team to cafeteria or order lunch after team arrives; most will want working lunch
• Transportation between sites may be handled in a variety of ways
Cytopathology Inspectors

Must verify all personnel who examine Pap tests:

1. Have successfully completed Gyn PT in the past year
2. Are enrolled for the current year
3. And who require retests, have completed it successfully in specified time period (45 days from notification of failure)
Scenario

• Attachment B
Inspection Pointers

• Remember, the CAP LAP is a peer review process which focuses on education and a supportive inspection
• Be courteous, professional and honest
• Agree to disagree
Assistance

http://www.cap.org
Email: accred@cap.org
800-323-4040, ext. 6065
Thank You

Questions?