CAP Cytopathology Checklist: Hitting A Moving Target

AP108 Current Issues in Gynecological Cytology

Theresa M. Voytek, MD
Hartford Hospital

© College of American Pathologists 2004. Materials are used with permission of Theresa M. Voytek, MD.
**Cytology Checklist Updates**

- Biannually
- Updated CLIA regulations
- Development of new technologies
- Response to participant and inspector questions
- [www.cap.org](http://www.cap.org)-- current and proposed checklists
Today’s Topics

- Quality Assurance/Improvement
- Reporting
- Instrumentation
- Common deficiencies and helpful hints
QC/QA Monitors

- Enrolled in PAP and CAP non-gyn programs or equivalent
- Hierarchical review: written criteria
- Rescreening
- Retrospective review
- Cytologic/histologic correlation and correlation with clinical findings
- Individual evaluation compared to lab
- Documentation/thresholds/corrective action
5 Year Retrospective Review

• All cases of HSIL+ on Pap: rescreen prior NIL Paps
• Questionable slides reviewed by pathologist, who may consult others for less biased opinion.
• Original technologist/pathologist involved--educational process
• QA records: discrepancy defined as one that affects current patient care.
• Amend report or notify physician only if discrepancy affects current patient care.
Cytologic/Histologic Correlation

• Old CLIA: Comparison of all malignant and premalignant Pap results with histology reports

• New CLIA (2003): Comparison of gyn reports with HSIL+ with available clinical information and with the histopathology report, if available, with determination of cause of any discrepancy.
Cyto/Histo Correlation

- Example: Pap interpretation HSIL, cervical biopsy negative.
- Review Pap and biopsy to determine cause of discrepancy.
- If Pap dx of HSIL is confirmed, and biopsy determined to be sampling error, clinician may proceed with definitive treatment
- Biopsy not always “Gold Standard”
Workload Limits

• 100 maximum slides per day for manually screened gyn and non-gyn slides (12.5/hr)
• Non-gyn concentrated and liquid-based preps covering < 1/2 of slide surface may count as 1/2.
• Gyn liquid-based count as whole slides
• 200 maximum computer-assisted Pap screening, Cytyc Imager (25/hr)
Workload Limits

• Includes all gyn primary screens, 10% rescreens, 5-year retrospective rescreens and all non-gyn slides
• Part-time employees and those with other duties have workload calculated based on screening time
• Pathologists performing primary screening or 10% QC rescreening must adhere to workload limit.
Workload Limits

• CLIA/CMS sets absolute maximum limit
• NOT a productivity goal
• Individual workload limits set every 6 months, based upon 10% rescreen and pathologist-cytotechnologist correlation data (CLIA requirement)
• Other factors: Experience, ability, comparison data, competency assessment, additional duties impacting screening time
TAT

- 90% of reports on routine non-gyn cytology cases completed within 2 working days
- Longer TAT allowed for cases requiring additional work-up or special circumstances (defined by laboratory)
- TAT not specified for gyn cytology
Statistical Analysis

• Annual statistics by type and source (Minimum is Gyn and Non-gyn case numbers)

• Gynecologic Cases:
  – by interpretive categories (including unsat)
  – Significant cyto/histo discrepancies
  – Rescreen reclassification as SIL+
  – Cases of HSIL+ with histology correlation
## CAP 2003 Benchmark Data
### Conventional
#### Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>50th</th>
<th>95th</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASC-US(%)</td>
<td>0.5</td>
<td>3.1</td>
<td>9.7</td>
</tr>
<tr>
<td>ASC-H(%)</td>
<td>0.0</td>
<td>0.1</td>
<td>2.1</td>
</tr>
<tr>
<td>LSIL(%)</td>
<td>0.3</td>
<td>1.4</td>
<td>5.6</td>
</tr>
<tr>
<td>HSIL(%)</td>
<td>0.1</td>
<td>0.4</td>
<td>2.2</td>
</tr>
<tr>
<td>ASC/SIL+</td>
<td>0.5</td>
<td>1.4</td>
<td>3.7</td>
</tr>
<tr>
<td>AGC(%)</td>
<td>0.0</td>
<td>0.2</td>
<td>1.3</td>
</tr>
<tr>
<td>UNSAT(%)</td>
<td>0.0</td>
<td>0.5</td>
<td>3.1</td>
</tr>
</tbody>
</table>
### CAP 2003 Benchmark Data
Liquid-Based Preparations
Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>50th</th>
<th>95th</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASC-US(%)</td>
<td>0.9</td>
<td>4.1</td>
<td>11.0</td>
</tr>
<tr>
<td>ASC-H(%)</td>
<td>0.0</td>
<td>0.2</td>
<td>1.5</td>
</tr>
<tr>
<td>LSIL(%)</td>
<td>0.8</td>
<td>2.4</td>
<td>6.9</td>
</tr>
<tr>
<td>HSIL(%)</td>
<td>0.1</td>
<td>0.5</td>
<td>2.0</td>
</tr>
<tr>
<td>ASC/SIL+</td>
<td>0.4</td>
<td>1.3</td>
<td>3.1</td>
</tr>
<tr>
<td>AGC(%)</td>
<td>0.0</td>
<td>0.2</td>
<td>1.0</td>
</tr>
<tr>
<td>UNSAT(%)</td>
<td>0.0</td>
<td>0.4</td>
<td>1.6</td>
</tr>
</tbody>
</table>
ASC/SIL

• Useful ratio for interlaboratory comparison
• Checklist Question: If the lab’s annual ASC/SIL+ is outside the 5th-95th percentile (0.5-3.7 for conventional and 0.4-3.1 for liquid-based), has the lab determined and documented the reason? (Phase I)
• ASC/SIL+ may be influenced by patient population (high risk vs. low risk)
Cytopathology Reporting

• Contents of cytopathology report
• Educational notes and recommendations
• Report Signatures
Cytopathology Reports

- Name/unique identifying number/accession #
- Birthdate/age/gender
- Physician and/or clinic
- Name of reviewing pathologist, when applicable
- Name and address of lab where test performed
- Anatomic source/type of specimen
- Test performed and date of report
- Basis for correction/amendment, if applicable
Cytopathology Reports

• Interpretation (descriptive terminology)
• Space for comments/recommendations
• Other desirable elements:
  – Date of specimen collection
  – Date of lab receipt
  – Description of specimen on receipt
Recommendations/Educational Note

• Recommendations for patient management in accordance with guidelines published by national medical societies (ie. ASCCP)

• Education of providers that the Pap test is a screening test for cervical cancer with an inherent false negative rate
  – Preferred mechanism is note on negative Paps
  – Alternatives include sending periodic educational info. to providers, conferences, etc

- Names/signatures on diagnoses only for those who examined the slides
- Medical directors name not associated with the diagnosis unless he/she personally examined the slides
- Cytotechnologists who screened the case identifiable in lab records
- Electronic signatures must be authorized by the pathologist who performed the review
Instrumentation: Slide Preparation and Screening Instruments

- Ongoing evaluation of instrument function and maintenance
- Adherence to manufacturer’s protocol for implementation
- Documentation of appropriate technical and interpretive training
- Written procedure to verify performance of automated screening instruments
Instrumentation

• Automated screening systems (II) NEW
  – If tolerance limits exceeded, is there documentation of corrective action?
  – Documented procedure for handling workload during instrument failure
  – Documented procedure for handling slides not successfully processed
  – “Negative” slides subject to 5 year retro review
Most Common Deficiencies

Phase II: Documentation of annual review of policies and procedures by the director or designee
Most Common Deficiencies

Phase I: Policy to educate providers that the Pap is a screening test with false negatives
Most Common Deficiencies

Phase I: Laboratory enrolled in peer educational program in non-gyn cytopathology

(ie. CAP NONGYN Program)
Most Common Deficiencies

Phase I: Sufficient space for processing cytologic material. May get you more space!
Inspection Preparation Tips

- Inspection based on checklist mailed to your lab (not necessarily the latest version on CAP web site)
- Use web site for explanatory notes/commentary—Your inspector probably will!
Inspection Preparation Tips

• Check CAP web site periodically for checklist updates to be prepared for upcoming changes
• Create a calendar of reminders to assure compliance with CLIA and checklist
• It doesn’t exist if it isn’t documented!
Example Cytology Calendar

**January**
3-7 Prepare annual statistical report for 1994
17-21 Cytotech competency assessments

**February**
7-11 Cytoprep competency assessments
Example Cytology Calendar

**March**
8-12  Cytotech workload limit assessments

**April**
11-15 Review/update policies/procedures

**May**
13  Cytotechnologist Day!
Pearls of Pathology

- Develop QA/QI program that works for your laboratory
- Use published benchmark data, CLIA, CAP checklist updates as resources
- Document, document, document!
- Inspections: Educational experience, opportunity to improve