Quality Improvement and Risk reduction in Cytology laboratory: The why and how of what we do

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For This talk

- Historical perspective
- Current regulations
- Accrediting Agencies
- Check lists and questions for cytology lab
- Strategies to improve quality and reduce risks for patients, lab and pathologists
- QA Indicators and Examples

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 Braden's Staff Reporter of The Wall Street Journal

Nov 2, 1987
What is CLIA 88?
Clinical Laboratory Improvement Amendments of 1988
The Clinical Laboratory Improvement Act was in 1967

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
- Statistics
- Proficiency Testing
And, To Enforce The Regs....

Cytology Specific Inspections!

Personnel Standards

- **Technical Supervisor**, M.D or D.O certified in AP by ABP or ASC with state license
- TS must confirm dx of reactive/repair and ECA categories and review all non Gyn cytology cases.
- **General Supervisor** may be the TS or a CT with 3 yrs of full time experience in cytology.
- GS involved in day to day supervision of lab & personnel. Document daily workloads.

Personnel Standards...

**Cytotechnologists** qualifications

- Graduated from school of Cytotechnology, accredited by CAHEA & certified by certifying agency approved by HHS (ASCP BOR).
- Before 1992....Possess state license.
- Documents results & total # of slides screened/24 hr.
- # of hrs/24 hrs spent reviewing slides.
Personnel Standards...advantages
- Standardized personnel requirements, hence no room for unqualified people screening
- Put lab operations in charge of cytology professionals
- Grandfathered in the senior professionals
- Accountability

Personnel Standards...disadvantages
- Too rigid...hence many overseas trained and practicing cytotechnologists excluded
- IAC exam not valid for employment in the US

CLIA 88 and Cytology
- Personnel Standards
- Workload Limits
- Hierarchical Review of slides
- Rescreen functions and performance evaluations
- Statistics
- Proficiency Testing
Maximum Workload Limits

- Traditional Smear......100 slides*
- Location Guided.........200 slides
- Combination............100-200 slides in no less than eight hours (i.e. daily workload records)
  - Workload reassessed at least every 6 months
  - Some states like NY and CA have lower limits of 80 slides
  - Liquid based Gyne specimens considered 1 slide. Non Gyne ½ slide

Workload Limits...Pros and cons....

Pros:
  - No more abuse by CTs or Labs
  - Did away with payment per case
  - Fewer “missed” cases

Cons:
  - Large commercial labs mandating a quota
  - How much is too little?

CLIA 88 and Cytology

- Personnel Standards
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Review of Slides

• Hierarchical Review
• 10% Rescreen
• Retrospective review/HSIL lookbacks
• Cytology Histology Correlations

Hierarchical Review

• Pathologist reviews all Non Gyne and Fine Needle Aspiration cases
• For Gyne, all Epithelial Cell Abnormalities and Reactive/repair
• Mechanism for resolving discordant diagnosis between Pathologist and Cytotechnologist

10% Prospective Rescreen (Gyn)

• Performed on negative cases not being sent for Hierarchical review.
• Done prior to reporting the case
• Done by Technical or general supervisor or designee.*
• Should include a % of high risk cases.
• Document results and remedial measures if required.

* CT with 3 yrs full time experience, senior resident or cytopathology fellow
Hierarchical Review and 10% Rescreen: Pros and cons

Pros:
- Standardized
- Non Gyne considered diagnostic testing

Cons:
- 10% rescreen not as efficient
- However, unable to do 100% rapid rescreen or presecreen due to workload limits...each slide counts as one.

Five Year Retrospective Rescreen

- Review previous negatives in current cases with abnormalities (HSIL and Cancers)(Gyne only)
- Type of error: None Vs screening Vs interpretive
- Document Statistics
When does one do Amended/Revised/Corrected Reports in Retrospective Rescreen?

Only if it makes a difference in current clinical management

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Pros...
- Good QA activity from which one is expected to learn
- Best interest of patient

Cons...
- Huge litigation boondoggle
- Is 5 yrs too much? Or should it be 2 or 3 years?
Ideal Number of Years for Five Year Retrospective Rescreen/ Lookback

- 86-94% of false negatives occurred within 3 years prior to Current HSIL/CA
- Screening problem most common in cases diagnosed previously as normal
- Interpretive discrepancy predominated when previous diagnosis was Benign cellular changes (Jones 1995)

Refs: Jones et al. Arch Pathol lab med Vol119; 1097-1103
Allen K et al. Am J clin Path vol101; 19-21
Tabbara and Sidawy. Diagnostic cytopathology. Vol 15;7-11
Montes, Cibas et al. Cancer Vol 87;56-59

Cytology Histology Correlations

- Mandated for HSIL & carcinomas (Gyne and Non Gyne and FNAs)
- Good QA practice
- Good patient care
- Different ways and timelines for doing the correlations
- Varies by institutions and practice settings

Participant Practices Regarding Cytology Histology Correlations

Correlations performed and documented at

- At time of biopsy signout ________ 60.7%
- After biopsy is reported ________ 22.4%
- Both of above ________ 17%
- Correlation documented in Bx report ________ 42%
- Discrepancy routinely documented in Bx report ________ 66%
Additional resources…current

Quality Improvement Opportunities in Gynecologic Cytologic-Histologic Correlations
Findings From the College of American Pathologists Gynecologic Cytology
Quality Control Conference Working Group I

Calculate the Positive Predictive Value
CLI A 88 and Cytology

- Personnel Standards
- Workload Limits
- Hierarchical Review of slides
- Rescreen functions and performance evaluations
- Statistics
  - Proficiency Testing

Statistics

- Annual Gyn and Non Gyn cases (by specimen types)
- Breakdown of Gyn cases including Unsatisfactories
- # of cases where the 10% or retrospective rescreen yields positive diagnosis
- Cyto-histo correlates and reasons for non correlates.

Performance Evaluations and Setting Workload Limits

- To be done at least every 6 months (for Cytotechnologists)
- By Technical supervisor (MD)
- Use 10% rescreen stats, HSIL/Ca look back results and comparison of cytotechnologists to laboratory reporting rates and stats
Cytology Proficiency Testing..Pros

- Ensure Public safety and confidence
- Supposed to have weeded out the incompetent Pathologists and Cytotechnologists

Cytology Proficiency Testing...Problems

- Glass slide based
- On site
- No field validation of slides requirement initially (only 2 anatomic pathologists have to agree and biopsy in ECA cases)
- Scoring grid outdated and gaming
- 10 slide test statistically meaningless!
- Frequency and expense

Note: 10 slide test statistically meaningless.
2008 data from CAP program which is 67% of participants.
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Major Regulatory Agencies

- CMS-Responsible for enforcing provisions of CLIA 88
- FDA (Blood bank, mammography, pharmacy)
- OSHA

And Finally, Enforcement of the Regs!

- CMS contracted ASCT to do cytology Inspections when complaints or when requested by local/state inspectors
- 1-800……toll free number for anonymous complaints…

CMS= Center for Medicare and Medicaid services, FDA=Food and Drug Administration
**Cytology Lab Inspection Statistics**

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

*Above based on self reported application data to CMS (4/23/2009)*

Resources…

Published 2005 by CAP
Update in 2015-16

Updated chapter coming in 2016-17 edition

Resources…

2014
General elements of QI

- Defined QI plan with active surveillance
- Technical and procedural elements (QC): proper integrity of specimen and high quality preparation
- Professional activities and the roles of the cytotechnologist and pathologist: Monitors related to quality interpretation & reports
- Interlaboratory comparison, self-assessment, and consultation activities

Checklists and Deficiencies

- Phase 0: Informational
- Phase 1: Should be corrected if possible, but deficiency may not seriously affect quality of patient care or welfare of worker
- Phase 2: Major deficiencies, labs must document corrective action
- Recurring deficiencies are serious
LAP Cytopathology Checklist
- General Cytopathology
  - Quality Improvement
  - Quality Control including instrumentation
  - Personnel
  - Physical facilities
  - Laboratory Safety
- Gynecologic Cytology
- Non-gynecologic Cytology
- To download checklist go to www.cap.org

LAP Cytopathology Checklist
- Pre Analytic
- Analytic
- Post Analytic
Specimen Collection and Receipt (Pre Analytic)

- Specimens/Patients properly identified
- Instructions available for preferred specimen collection/preparation
- Requisition: complete data requested including date, source, physician, pertinent clinical information, etc.
- Criteria for specimen rejection and notification of unacceptable specimens

Non-Gynecologic Cytopathology Phase II (Pre Analytic)

- Instructions for collection of non gyn specimens (sputums, FNAs etc)
- Are these available at all sites where specimens are collected (nursing stations, physicians offices, endoscopy units etc)

Example of Inspection Questions and Documentation
**Retention Guidelines (Post Analytic)**

- Glass slides: 5 years
- FNA slides: 10 years
- Reports: 10 years
- Accession logs / worksheets: 2 years
- Maintenance records: 2 years
- Service / repair records: life of instrument

**Benchmarking: Checklist Question (Post Analytic)**

- If the lab’s annual ASC/SIL is outside 5th-95th percentile (0.4 - 5.1), has the laboratory determined and documented the reason?
### Reporting Rates in CAP PAP Labs (Conventional)

<table>
<thead>
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<th>Category</th>
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<th>Median</th>
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<td>HSIL</td>
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<td>2</td>
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<tr>
<td>ASC/SIL</td>
<td>0.4</td>
<td>1.7</td>
<td>4.5</td>
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### Reporting Rates in CAP PAP Labs (ThinPrep)

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### Other Benchmarking Means

- High Risk HPV positivity rates for ASC-US
- Compare Your lab with others (benchmarking data provided by CAP)
- Compare rates by individual cytotechnologists and Pathologists
- Too low or too high, reason for concern and remediation
CAP LAP Non-Gynecologic Cytopathology (Analytic)

- Papanicolaou or other permanent stain (CYP.07685) (Phase II)
- Documented policy for ensuring that nongyn specimens with a high potential for cross-contamination are processed and stained separately

Non-Gynecologic Cytopathology Phase II (Analytic)

- All nongyn slides reviewed by pathologist (CLIA88)
- Non Gyn (Exfoliative and FNAs) is diagnostic cytology and considered practice of medicine
- Non Gyn Statistics

Non-Gynecologic Cytopathology Phase II (Post Analytic)

- Effort to correlate nongyn specimens with histological and clinical findings
- If significant disparities, these should be reconciled in a confidential peer-reviewed QI document
Non-Gyn: Phase I Questions (Post Analytic)

- Is the laboratory enrolled in or has it attempted to enroll in a peer educational program in Non-Gynecologic cytopathology

Non-Gyn: Questions

- Are 90% of reports on routine non-gyn cytology cases completed within 2 working days of receipt by laboratory?
  - Greater reporting time allowed for specimens requiring special stains or processing, and those from patient/specimen types for which longer TAT is clinically acceptable (lab must define) Discontinued……but most labs follow anyway
  - Periodic audits or continuous monitors
Most Common Deficiencies in Cytology

Is there a written policy for ensuring that non-gynecologic specimens with a high potential for cross-contamination are processed and stained separately from other specimens?

Most Common Deficiencies in Cytology continued

Is there documented evidence of daily review of the technical quality of cytologic preparations by the pathologist or supervisory level cytotechnologist?

Most Common Deficiencies in Cytology continued

Is there documentation of at least an biennial review of all procedures in the cytopathology laboratory section by the current laboratory director or designee?
Unannounced Inspections

- LAP started conducting unannounced inspections in 2006 (every 2 years)
- CAP also does unannounced inspections when serious quality questions arise
- TJC also initiated unannounced inspections in 2006

Note CAP-LAP has been doing inspections since before CLIA'67

CAP Notification

- Lab must notify CAP of:
  - Adverse media attention (e.g., newspaper articles, TV “expose”, etc.)
  - Investigation by state or federal agency
  - May trigger a CAP reinspection, which may be unannounced
- CMS does 10% re inspections within 1 month of inspection by any accrediting agency (QC on agency)

Instrumentation

- Evidence of active review of results of instrument maintenance and function (II)
- Automated instruments (II)
  - Documentation of adherence to manufacturer’s recommended protocol for implementation
  - Documentation of appropriate technical and interpretive training
  - Written procedure to verify diagnostic & adequacy performance of screening instrument
**Instrumentation**

- Evidence of active review of results of instrument maintenance and function (II)
- Automated instruments (II)
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  - Documentation of appropriate technical and interpretive training
  - Written procedure to verify diagnostic & adequacy performance of screening instrument
  - Keep validation records for life of instrument

**Web Cams for Rapid On Site Evals**

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The goal of the Quality Management Plan is to provide a means of monitoring the accuracy and completeness of diagnostic reporting by members of The Methodist Hospital cytopathology staff and to identify potential areas for improvement. Results of monitoring will be reported at the Department of Pathology service meetings and disseminated to the participants, Pathologists and Cytotechnologists on a quarterly basis or as deemed necessary. In addition, variant reports in clinical practices identified in the monitoring processes are communicated through the Director of Cytopathology, to the Quality Management committees of The Methodist Hospital Medical Staff.

Components of the plan for 2011 include the following:

(A) Monthly monitoring of quality management indicators:
1) Cytopathologist to cytotechnologist correlation (gynecologic only)
2) Cytology-Histology correlation (gynecologic and nongynecologic)
3) Turnaround time (nongynecologic)

(B) Quarterly monitoring of quality management indicators:

1) Peer review Cytopathologist
2) Documentation of consultations (intra-departmental and extradepartmental)
3) HPV positivity rates (by lab and individuals)

(C) Site-specific reviews (semi-annual if indicated)

1) Salivary
2) Respiratory

(D) CT Evaluation and Workload Limits (six monthly)

(E) Continuous mechanisms of quality improvement:

1) HSIL/carcinoma look backs (gynecologic specimens)
2) Incomplete requisitions/Missing clinical information
3) Patient report review, TAT

(F) External audit mechanisms:

1) CAP inter-laboratory comparison program in gynecologic cytology
2) CAP inter-laboratory comparison program in non-gynecologic cytology
3) CAP PT in gynecologic cytology

(G) Annual statistics summary (gynecologic, nongynecologic, and FNAs)

The results of all monitors are summarized in annual reports with emphasis on identifying trends and target areas for improvement. Areas of concern, if any, are reviewed at the monthly working meetings of the cytopathology staff in order to formulate strategies for improvement. Recommendations will be submitted as a formal report to the Department of Pathology service meetings. The plan is designed to conform to the TJC Model for continuous improvement of hospital services (JCAHO, Chicago, IL, 1988).
Table 1

<table>
<thead>
<tr>
<th>TABLE OF CYTOPATHOLOGY TEST PERFORMANCE</th>
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<td>Test Category</td>
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Table 2

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Table 3

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Table 4

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Categorization of Errors(variances) in Cytology

Category I: Clerical errors
No impact on patient care.
Spelling or syntax errors resulting in confusing or ambiguous report
Failure to document special stains/immunos/cell block/flow cytometry

Category II: Minor reporting errors.
No impact on patient care.
Spelling or syntax errors resulting in confusing or ambiguous report
Failure to document special stains/immunos/cell block/flow cytometry

Category III: Diagnostic discrepancies
Original and reviewing pathologist agree diagnosis erroneous
Error unlikely to adversely affect treatment or follow up.

Category IV: Major diagnostic error
May result in inappropriate management if not immediately corrected. Call to treating physician and amended report warranted.

Lind and Travers
Indicators

For each indicator, the following data should be provided:

1) A statement of the performance issued to be addressed (for example, turnaround time);
2) The frequency with which the data would be collected (for example, monthly, quarterly, annually, etc.);
3) Methods for acquiring and analyzing the data;
4) Threshold or action level; and
5) The frequency and mechanism of data reporting.

Example:

Peer Review

- Prospective (Intra or extra departmental consultations)
- Retrospective
- Random (Every 10th or 50th case)
- Focused/site specific
**Retrospective Review**

Performed after case is signed out
Lab director decides parameters
- May be random or directed
- % of cases to be reviewed
- Who does it, how often and whom/where is it reported?
- Action to be taken depending on trend noted
- Re evaluate after implementation of changes

**Site Specific/ Focused review**

- Usually retrospective
- Includes all factors (Preanalytic, Analytic and Post analytic) or can be limited to just diagnosis
- Once issues are discovered, implement a plan to fix it
- After a certain period, re evaluate to see if plan works

**Lab Statistics**

- Statistics of the different specimen types and their breakdown by diagnosis is recommended.
- Tracking of unsatisfactories/Non diagnostic cases can be helpful.
- If a trend is noted which can be acted or improved on then action needs to be taken.
- Re evaluate after plan /changes implemented
**Turn Around Time (TAT)**

- This is a sensitive indicator of the entire process of system organization and function, i.e., from specimen collection to reporting and charting.
- TATs have to be established in consultation with the pathologists and cytotechnologists for the various types of specimens.
- Thresholds have to be set for the different types of specimens.
- TATs should be monitored monthly for the entire lab.
- Deviations from these should be investigated.
- If necessary, TATs can be tracked by pathologist, technologist, courier, prep time etc. (Pre analytic, analytic, post analytic)

**Cytology-Histology-Clinical Correlations**

- Documented attempts should be made to correlate the cytologic diagnosis with the current or previously resected histologic material when available.
- Every attempt should be made to obtain correlation on positive and suspicious cytologies.
- Cytologic material with infectious organisms should be correlated with microbiologic culture results when available.
- In discrepant cases, reasons should be sought and resolved i.e., sampling vs interpretive. If interpretive, then appropriate actions need to be taken.
- Action in the form of addendum reports or counselling or CME activity for individuals or the group should be implemented if and when necessary.
- Amended reports if it makes a difference in the current clinical management

**Continuing Medical Education**

- Journal subscriptions
- Internal conferences
- Teleconferences/Webinars
- Meetings and review courses
- Mailed educational programs