


Cytology QA: What Works and What Doesn't! The U.S Experience

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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

Nov 2, 1987

CLIA '88 and Cytology

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

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

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 1/2 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?

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

EDITORIAL
 Section Editor: Tilde S. Kline

"Workload Limits" and CLIA 88 in the 1990's: How Much Is Too Much? Or Too Little?
 Dina R. Mody,^{1*} M.D., Diane D. Davey,² M.D., and Tilde S. Kline,³ M.D.

"Workload Limits" and CLIA 88 in the 1990's: How Much Is Too Much? Or Too Little?
 CONDITION: CYTOLOGY-493.1257(b)¹ The laboratory is responsible for ensuring that each individual engaged in the evaluation of cytology preparations ... examines no more than 100 slides (gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual.
 COMMENTS: "Some were concerned that the 8 hour limit may have an adverse effect on quality as some laboratories may make 8 hours a target time period for cytotechnologists to screen the workload minimum."
 RESPONSE: "We emphasize again that this is an absolute maximum and is not to be construed as a target number of slides for every individual."
 wasn't unanimous. Some cytotechnologists felt that they could screen their 100 slides in less than 8 hours and should be allowed to do extra duties around the lab or leave for the day. Others, however felt pressured to screen the maximum workload, and additional duties were not always taken into account. A clarification in the rule stated that the workload should be prorated for individuals who do not screen slides 8 hours per day. The maximum workload in these situations was to be calculated per hour with the upper limit being no more than 12.5 slides per hour. In other words, if the cytotechnologist spent 6 hours screening, and 2 hours in the prep room, that cytotechnologist could screen no more than 75 slides per day (12.5 slides per hour x 6 hours = 75). The rule additionally stated the director must assess workload for each screening cytotechnologist every six months based on an individual's capabilities and performance evaluation.
 One would think that the issue was finally resolved. Alas it wasn't! Although many cytotechnologists could complete

Diagnostic Cytopathology Vol 16 (1) 1-2 1997

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Hierarchical Review

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

10% Rescreen

- 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 precreen due to workload limits...each slide counts as one.

Five Year Retrospective Rescreen

- Review previous negatives in current cases with abnormalities (HSIL and Cancers)
- 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

Five Year Retrospective Rescreen, Pros and cons..

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
- 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%

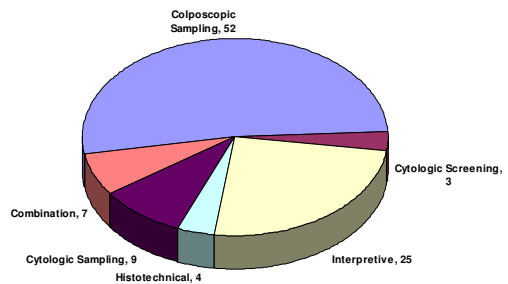
Jones B, Novis D. Cervical biopsy cytology correlation. A CAP Q probes study. Arch Pathol Lab Med. Vol 120 1996. 523-530

Cervical Biopsy–Cytology Correlation, a CAP Q probes study of 22439 correlations in 348 labs

Biopsy Dx	Cytology Diagnosis(%)			
	Neg	ASC/G	I	II+
NILM	67	37	21	5
LSIL	26	44	60	7
HSIL+	7	14	18	88

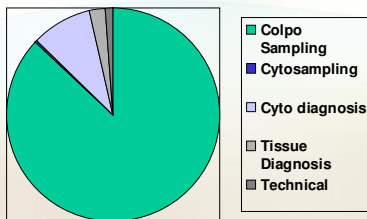
Jones B, Novis D Arch pathol lab med vol 120 1996, 523-531

Etiologies for Non-Correlating Cervical Cytologies and Biopsies



Tritz D et al. Am J of Clin Path. Vol 103; 1995 594-597

Reasons Cytology Histology Non Correlation (HSIL+) at Methodist Hospital (2000-2007)



N=344, Colpo sampling 87%, cytodagnosis 9.3%

From charity clinic operated by residents in training

Factors Influencing Accuracy of Colposcopy Guided Biopsy

- Severity of Referral Pap
- Patient age and menopausal status
- Visibility of Squamo columnar junction
- Lesion Size
- Endocervical extension
- Training and experience of colposcopist
- Type of clinician

Gage J et al. Obstetrics & Gynecology Vol 108, No2, 2006 pp264-272
Costa et al. Gynecologic oncology Vol 90, 2003. pp 57-63

CLIA 88 and Cytology

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- **Statistics**
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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**

Proficiency Testing

- On site, annual
- 10 slide set with a pass score of 90%
- Retest with 10 slides within 45 days
- Two failures results in 20 slide test
- All pap smears reexamined
- 3rd fail, 35 hrs CME, 20 slide exam
- No screening in the meantime.

Cytology PT results 2005-2008 (first 10 slide test)

Category	2005	2006	2007	2008
All	~95	~95	~95	~95
CT	~95	~95	~95	~95
PTH	~95	~95	~95	~95
PriPTH	~67	~85	~95	~95

*Note 10 slide test statistically meaningless
2008 data from CAP program which is 67% of participants*

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

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...

ASCT/CMS Inspections

- Team of Cytotechnologists show up*
- Huge disruption for labs
- 1% or minimum of 100 slides rescreened
- Usually last for 3 days
- 34% initially found to have deficiencies
- 4% upon review..final
- Lab closures...drove out the small players
- Pap mills got even bigger...

** Team pathologist off site available by phone, files in if required*

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)

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

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

Retention Guidelines

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

- If the lab's annual ASC/SIL is outside 5th-95th percentile (0.4 - 5.1), has the laboratory determined and documented the reason? (Phase I) CYP.07650

Reporting Rates in CAP PAP Labs(Conventionals)

Category	5%tile	Median	95%tile
Unsatisfactory	0.0	1	5.9
ASC-US	0.3	2.4	8.2
ASC-H	0.0	0.2	1.5
LSIL	0.3	1.3	6.7
HSIL	0.1	0.3	2
AGC	0.0	0.1	1.1
ASC/SIL	0.4	1.7	4.5

Reporting Rates in CAP PAP Labs (ThinPrep)

Category	5%tile	Median	95%tile
Unsatisfactory	0.1	1.1	3.4
ASC-US	1.7	4.9	11.5
ASC-H	0.0	0.3	2
LSIL	1.1	3	7.3
HSIL	0.1	0.6	2.0
AGC	0.0	0.2	1.4
ASC/SIL	0.7	1.5	3.4

Reporting Rates in CAP PAP Labs (SurePath)

Category	5%tile	Median	95%tile
Unsatisfactory	0.1	0.3	1.3
ASC-US	1.7	4.1	12.8
ASC-H	0.0	0.3	0.8
LSIL	1.1	2.5	7.7
HSIL	0.1	0.3	1.2
AGC	0.0	0.2	0.7
ASC/SIL	0.7	1.6	2.8