### Image assisted cervical screening
- Fully integrated interactive computer IS designed to assist CTs in primary screening
- Image processor rapidly scans and locates FOV (10-22) for every slide
- CT evaluates all FOV
  - if no abnormalities → sign out as “Negative”
  - any abnormalities → require manual review of entire slide

### Image Assisted Paps and Market Share
- Estimated total Paps of 65 million (USA)
  - Conventional 10-15%
  - LBC 85-90%
    - ThinPrep 70-80%
    - 66% imaged by TIS
    - BD SurePath 20-30%
    - 50% imaged by GS FocalPoint

### CLIA and FDA
- FDA approved workload limits are doubled for image assisted Paps
- CLIA 88 workload regulations now recognize manufacturer’s labeling for workload levels

### How Many are too Many?
**Cytotech Workload Limits and Quality Indicators in the Age of Image Assisted Paps**

**Moderator:** Tarik M. Elsheikh, MD  
Director of Cytology  
Ball Memorial Hospital  
Muncie, IN

- With the current and projected shortage of CT workforce
- Desires to reduce laboratory costs, improve profitability, and under bid
- Increased productivity with image assisted primary screening became an attractive option for many labs
- Reducing QA/QC measures to the minimum required by CLIA, frees up more CTs for primary screening
Effectiveness of implementing image assisted screening may depend mostly on the speed with which slides are screened. Some labs are encouraging their CTs to meet designated productivity expectations, NOT “Quota.” Expectations are determined on an individual basis and do not represent a minimum required # of screened slides to be achieved consistently.

To: <members@lists.cytopathology.org>
Subject: RE: [ASC Listserv] Cytotech's Productivity (100% of slides are imaged)
Date: Tue, 23 Jun 2009 13:47:48 -0400

Do you count full manual review slides as ½ slide or 1 slide? Authoritative reference?
Some labs count all imaged slides as ½, whether only 22 FOV are reviewed, or the latter + full manual “rescreening” (aka review, screening).

Sent: Thursday, May 14, 2009 11:09 AM To: members@lists.cytopathology.org Subject: [ASC Listserv] Cytotech's Productivity

ALL:

Our lab is increasing the productivity expectations for our Cytotech’s. We have 100% ThinPrep slides and our slides are 100% imaged. What did other labs do to increase your staff's productivity?

Effect of increased workload on CT performance

- Direct relationship between the amount of time spent screening slides and the accuracy of the reading
  - It is generally accepted that increased workloads \(\rightarrow\) reduced accuracy \(\rightarrow\) increased FNR
  - Are CLIA 88 regulations enough to monitor screening accuracy?

Assessment of CT workload, according to CLIA 88

- FNR from 10% negative rescreen
  - is not particularly effective in documenting performance because # of missed SIL is low
  - it could take more than 10 years to identify a CT with high enough of an error rate.
- Level of *pathologist-C T concordance* on referred cases
  - Evaluates interpretive skills not screening performance
Questions need to be Addressed regarding Image assisted Paps

1. What is the current and potential future trend of increasing CT workloads, especially in face of a shrinking work force?
2. What should be the maximum screening limit for a CT, without sacrificing quality?
3. If CLIA mandated QC requirements are insufficient, by themselves, how can we accurately monitor CT performance?

Current Issues in Cytology

- Ann Moriarty, MD
  - How the heck did we get HERE? Workload limits and safety
- Blair Holloday, PhD, SCT(ASCP)
  - Environmental scan of state of cytotechnology profession
- Fern Miller, CT(ASCP)
  - What is a realistic and reasonable workload limit?
  - Counting imaged Paps, per CAP and CLIA?

Questions/Discussion
9-10:00 AM – BREAK

10:00 AM
- Andrew Renshaw, MD
- Marshal Austin, MD, PhD
  - Optimal quality measures for assessing CT performance
- Tarik Elsheikh, MD
  - Summary
  - Questions/Discussion

How the Heck did we get Here? Work load limits and safety

Ann T. Moriarty, MD

Looking Backwards: Timeline

- Pre-CLIA, Pre Bogdanich
- The Bognanich year
- CLIA
- Post CLIA
- Post CLIA Automation

Cytotechnologist Bulletin

EDITORIAL
The Daily Screening Capacity
Of the Cytotechnologist

Let us hope that the ongoing vital question of quality control rather than the quantity control will receive more appreciation in the future.

Catherine M. Keesler, C.T.(ASCP)
ASC activities
- 12,000 patient slides per year
- Certified 40 labs
- NCI supported limit
- California:
  - 75/day or 50-2 slide cases
- NY proficiency test

40 cervical cases (80 slides)
2-3 NGC (4+ slides/case)
1 student
2 aspirates
QC as time available
Performance Levels
False Negative
Severe dysplasia/CIS not referred
Evaluation Characteristics
Within 2 diagnostic categories

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!

ASC response

CLIA ‘88
October 31, 1988; President Ronald Reagan

§ 493.1257 Standard: Cytology; Level II tests.
(1) Each individual engaged in the evaluation of cytology preparations by non-automated microscopic techniques who examines no more than 120 slides, which include both gynecologic and nongynecologic preparations, in a 24-hour period irrespective of the site or laboratory. Of the slide limit established.

CLIA ‘88 Final Rules (Jan 24, 2003)

§ 493.1274 Standard: Cytology.
(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be used as an individual’s performance target. In addition—
(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;
Productivity studies

- Med 9236 (38.5 slides/day)
- 90th percentile 15069 (62.8 slides/day)
- “higher error rates were associated with laboratories reporting higher ratios of gynecologic cases per cytotechnologist”

Jones, Davey Arch Pathol Lab Med: 1999;124: 672–681

Daily Workload Guidelines for Automated Assisted-Screening Technologies

- Include in pivotal clinical trials
- Safe and effective workload limits
- Statistical analysis
- Limits must be included in FDA application
- Methods to be used

February 24, 2003

ThinPrep (Hologic)

“...workload limit for the ThinPrep Imaging System has been established at 200 slides in no less than an 8 hour workday. The workload limit of 200 slides includes the time spent for manual review of slides that is not to exceed 100 slides in an 8 hour workday.” (June 6, 2003)


Sure Path Focal Point™ GS Imaging System

An individual...should not exceed 170 slides in a 24 hour period. The maximum number of 170 slides is examined in no less than an 8 hour work day. Manual workload limit does not supersede the CLIA requirement of 100 slides in no less than an 8 hour day per 24 hour period.”

- Review Profiler
- Location Confirmation of 1st FOV
- Screen 10 FOV’s
- Full slide review as needed
- Record results and triage appropriately
Patterns and Trends in Cytology

E. Blair Holladay, Ph.D., SCT(ASCP) CM
Vice President for Scientific Activities; ASCP
Executive Director, ASCP Board of Certification
Acting Director, ASCP Institute of Global Outreach

Retirement or Leaving the Field

<table>
<thead>
<tr>
<th>Retire or Leave Field</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘08</td>
<td>‘09</td>
</tr>
<tr>
<td>Less than 3 years</td>
<td>8.4</td>
</tr>
<tr>
<td>More than 10 years</td>
<td>88.1</td>
</tr>
</tbody>
</table>

Although the typical CT expects to retire or leave the field in more than ten years, there is an increase in the percentage of CT’s who expect to leave the field in less than three years.

GYN Volume

<table>
<thead>
<tr>
<th>GYN Volume</th>
<th>Percent</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘08</td>
<td>‘09</td>
<td>‘08</td>
</tr>
<tr>
<td>Increasing</td>
<td>23.1</td>
<td>24.7</td>
</tr>
<tr>
<td>Decreasing</td>
<td>31.4</td>
<td>32.8</td>
</tr>
<tr>
<td>Stable</td>
<td>33.5</td>
<td>31.1</td>
</tr>
</tbody>
</table>

A decreasing GYN volume has become the leading trend being reported by CT’s.
Non-GYN Volume

<table>
<thead>
<tr>
<th>Non-GYN Volume</th>
<th>Percent</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increasing</td>
<td>38.7</td>
<td>2</td>
</tr>
<tr>
<td>Decreasing</td>
<td>6.7</td>
<td>3</td>
</tr>
<tr>
<td>Stable</td>
<td>54.8</td>
<td>1</td>
</tr>
</tbody>
</table>

Most laboratories report a stable Non-GYN volume; however, it is clear that a decreasing Non-GYN volume has become more prevalent in the past year.

FNA Volume

<table>
<thead>
<tr>
<th>FNA Volume</th>
<th>Percent</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increasing</td>
<td>40.0</td>
<td>1</td>
</tr>
<tr>
<td>Decreasing</td>
<td>6.6</td>
<td>3</td>
</tr>
<tr>
<td>Stable</td>
<td>33.7</td>
<td>2</td>
</tr>
</tbody>
</table>

FNA numbers are consistent with last year; however, an increasing FNA volume is the most common trend.

Pap Tests performed

<table>
<thead>
<tr>
<th>Number of Pap Tests</th>
<th>Manual</th>
<th>ThinPrep®</th>
<th>BD PAP EXACT®</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20</td>
<td>375</td>
<td>544</td>
<td>83</td>
</tr>
<tr>
<td>21-60</td>
<td>328</td>
<td>393</td>
<td>44</td>
</tr>
<tr>
<td>61-100</td>
<td>122</td>
<td>113</td>
<td>23</td>
</tr>
<tr>
<td>101-200</td>
<td>0</td>
<td>35</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>821</td>
<td>899</td>
<td>160</td>
</tr>
</tbody>
</table>

CT's evaluate on average less than 60 slides per day regardless of manual versus imaged slides. There is a 3:1 ratio of TP versus BD imaged slides.

Type of Manual Screening Performed

<table>
<thead>
<tr>
<th>Type of Manual Screening Performed</th>
<th>Conventional</th>
<th>ThinPrep®</th>
<th>SurePath®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>55.56%</td>
<td>62.11%</td>
<td>35.58%</td>
</tr>
</tbody>
</table>

The most common manual screening is a ThinPrep® Pap Test.

Change in Cytotechnologists’ Duties in the last 3 years

<table>
<thead>
<tr>
<th>Added (% of respondents)</th>
<th>Removed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of imager systems</td>
<td>49%</td>
</tr>
<tr>
<td>Molecular testing (perform/assist/ supervise)</td>
<td>62%</td>
</tr>
<tr>
<td>Informal/technical related activities/ data management related activities</td>
<td>36%</td>
</tr>
<tr>
<td>Management/ supervision activities</td>
<td>29%</td>
</tr>
<tr>
<td>Cytoreduction (perform/assist/ supervise)</td>
<td>20%</td>
</tr>
<tr>
<td>Assist with RNA's</td>
<td>22%</td>
</tr>
</tbody>
</table>

49% of respondents report use of imager system being added to their job duties, while 42% report the addition of molecular testing and 37% report the addition of IT related activities.

Changes in the Cytotechnology Laboratory Portfolio in the last 3 years

<table>
<thead>
<tr>
<th>Added (% of respondents)</th>
<th>Removed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular diagnostic testing</td>
<td>46%</td>
</tr>
<tr>
<td>Pap imaging system</td>
<td>60%</td>
</tr>
<tr>
<td>Real-time technology</td>
<td>39%</td>
</tr>
<tr>
<td>Telediagnosis</td>
<td>18%</td>
</tr>
<tr>
<td>RNA service</td>
<td>15%</td>
</tr>
<tr>
<td>Teaching pathology centers / residents</td>
<td>16%</td>
</tr>
</tbody>
</table>

49% of respondents report an addition of molecular diagnostic testing to their laboratory’s portfolio, while 48% report an addition of Pap imaging system to their laboratory’s portfolio.
National Vacancy Rate for CT’s

<table>
<thead>
<tr>
<th>Position</th>
<th>Overall (all Laboratories)</th>
<th>4.8%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private clinic/reference laboratories</td>
<td>7.3%</td>
<td></td>
</tr>
<tr>
<td>Large hospitals</td>
<td>6.9%</td>
<td></td>
</tr>
</tbody>
</table>

ASCP Wage and Vacancy Survey; LABMEDICINE
March 2009; Volume 40: Number 3

Time to Refill Position Based on Level of Responsibility

<table>
<thead>
<tr>
<th>Position</th>
<th>Sample Size</th>
<th>Less than 3 Months</th>
<th>3 to 6 Months</th>
<th>6 Months to 1 Year</th>
<th>More than 1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Staff</td>
<td>(242)</td>
<td>49%</td>
<td>26%</td>
<td>22%</td>
<td>3%</td>
</tr>
<tr>
<td>CT Supervisor</td>
<td>(107)</td>
<td>51%</td>
<td>28%</td>
<td>9%</td>
<td>12%</td>
</tr>
</tbody>
</table>

ASCP Wage and Vacancy Survey; LABMEDICINE
March 2009; Volume 40: Number 3

CONCLUSION

The typical Cytotechnologist is:

A 45 year-old female (non-supervisory) cytotechnologist working in a large hospital/medical center laboratory that evaluates on average less than 60 slides per day - regardless of manual versus imaged slides

The following trends were observed regarding CT duties:

- Decreased GYN volume
- Stable-to-increased non-GYN volume
- Increased FNA volume
- Addition of molecular diagnostic testing
- Addition of Pap imager system

Future Trajectory of CT Scope of Duties
The following trends were observed regarding the laboratory portfolio:

- Use of an imager system
- Molecular testing
- Information technology related activities
- Management/Supervisory activities
- Cytopreparation
- Assisting with FNA’s

“Change is the law of life. And those who look only to the past or present are certain to miss the future.”

John F. Kennedy

What is a Reasonable and Realistic Workload Limit in the Age of Image-Assisted Pap Testing?

Fern S. Miller, MSM, CT(ASCP)
Metropolitan Pathologists PC

I do not have any affiliations or financial interest in any of the corporate organizations involved with products/services to which my presentation will refer in this program.

Workload Limits: Outline

- Counting Slides
- How suggested workload limits were determined
  - Laboratory Survey Information
  - Published literature
  - My laboratory
- Suggested workload limits
- Conclusion

Counting Slides

- Why am I so confused?
  - Literature is vague
  - Manufacturers’ information
  - Accrediting agencies not helpful
  - Speed limits are forgotten
### Current Maximum Daily Limits:

- **ThinPrep 22-FOV only:** 200 slides
  - 25 slides/hr = 2.4 min/slide
  - CLIA/CAP: .5 slide
- **FocalPoint GS 10-FOV only:** 170 slides
  - 21.25 slides/hr = 2.8 min/slide
  - CLIA/CAP: .5 slide
- **Full manual screen:** 100 slides
  - 12.5 slides/hr = 4.8 min/slide
  - 1 slide
- **FOV + full manual screen (autoscan):** 1.5 slides

### Regulatory Limits - ThinPrep Imaging

#### FOV Only and FOV + Full Manual Screen

<table>
<thead>
<tr>
<th>Examining Time</th>
<th>Slide Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hour Minutes</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>480</td>
</tr>
<tr>
<td>7.5</td>
<td>450</td>
</tr>
<tr>
<td>7</td>
<td>420</td>
</tr>
<tr>
<td>6.5</td>
<td>390</td>
</tr>
<tr>
<td>6</td>
<td>360</td>
</tr>
<tr>
<td>5.5</td>
<td>330</td>
</tr>
<tr>
<td>5</td>
<td>300</td>
</tr>
<tr>
<td>4.5</td>
<td>270</td>
</tr>
<tr>
<td>4</td>
<td>240</td>
</tr>
</tbody>
</table>

Ex: At 6 hrs, 18.2% full manual screen: 110 FOV slides include 20 FOV slides + manual screen

### Regulatory Limits - FocalPoint GS Imaging

#### FOV Only and FOV + Full Manual Screen

<table>
<thead>
<tr>
<th>Examining Time</th>
<th>Slide Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hour Minutes</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>480</td>
</tr>
<tr>
<td>7.5</td>
<td>450</td>
</tr>
<tr>
<td>7</td>
<td>420</td>
</tr>
<tr>
<td>6.5</td>
<td>390</td>
</tr>
<tr>
<td>6</td>
<td>360</td>
</tr>
<tr>
<td>5.5</td>
<td>330</td>
</tr>
<tr>
<td>5</td>
<td>300</td>
</tr>
<tr>
<td>4.5</td>
<td>270</td>
</tr>
<tr>
<td>4</td>
<td>240</td>
</tr>
</tbody>
</table>

Ex: At 7 hrs, 17.3% full manual screen: 116 FOV slides include 20 FOV slides + manual screen

### Survey/Literature/Lab

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Non-Hospital Labs: Image-assisted</th>
<th>Hospital Labs: Image-assisted</th>
<th>Total Labs: Image-assisted</th>
<th>Labs: Non-Imaged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labs</td>
<td>59</td>
<td>18</td>
<td>13</td>
<td>31</td>
<td>28</td>
</tr>
<tr>
<td>Techs</td>
<td>434</td>
<td>224</td>
<td>88</td>
<td>312</td>
<td>122</td>
</tr>
</tbody>
</table>
### Survey/Literature/Lab – Slides Screened/Hour

<table>
<thead>
<tr>
<th>Slides/Hr</th>
<th>Non-Hospital Image-Assisted Lab Average</th>
<th>Hospital Image-Assisted Lab Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-12</td>
<td>15%</td>
<td>88%</td>
</tr>
<tr>
<td>12-14</td>
<td>26%</td>
<td>8%</td>
</tr>
<tr>
<td>14-16</td>
<td>22%</td>
<td></td>
</tr>
<tr>
<td>16-18</td>
<td>37%</td>
<td></td>
</tr>
</tbody>
</table>

### Survey/Literature/Lab – Slides Screened/Day

<table>
<thead>
<tr>
<th>Slides/day</th>
<th>Non-Hospital Image-Assisted Lab Average</th>
<th>Hospital Image-Assisted Lab Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 60</td>
<td>34%</td>
<td>34%</td>
</tr>
<tr>
<td>60-80</td>
<td>24%</td>
<td>66%</td>
</tr>
<tr>
<td>81-100</td>
<td>44%</td>
<td>34%</td>
</tr>
<tr>
<td>101-120</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>121-140</td>
<td>18%</td>
<td>12%</td>
</tr>
</tbody>
</table>

### Survey/Literature/Lab – Imaged Workload Limits

<table>
<thead>
<tr>
<th>Slides/day</th>
<th>Non-Hospital Image-Assisted</th>
<th>Hospital Image-Assisted</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 100</td>
<td>44%</td>
<td>79%</td>
</tr>
<tr>
<td>100-120</td>
<td>38%</td>
<td>12%</td>
</tr>
<tr>
<td>121-140</td>
<td>18%</td>
<td>8%</td>
</tr>
</tbody>
</table>

### Survey/Literature/Lab – % Full Manual Screen of Imaged Slides

- % Labs: 70% Non-Hosp Imaged, 80% Hosp-Imaged
- Over 20%: 10%, 20%
- 15-20%: 30%, 40%
- < 15%: 40%, 50%

### Survey/Literature/Lab

- **Productivity:**
  - 81% labs increased 50%
  - 13% stayed the same
  - 6% decreased 10%
  - 25% labs increased 13%
  - 59% stayed the same
  - 8% decreased 15%
- **F/N Rate:**
  - 19% labs decreased 25%
  - 38% stayed the same
  - 6% increased 5.0%
  - 33% labs stayed the same

### Survey/Literature/Lab – 8-Hr Workday Activities

- Other Non-Screen
- Breaks
- Computer
- Screen
**Suggested Daily Maximum Limits:**

**Image-Assisted Labs**

- Maximum limits reduced by 45%
- FOV only:
  - ThinPrep: 110 slides @ 13.8/hr = 4.3 min/slide
  - FocalPoint GS: 94 slides @ 11.8/hr = 5.1 min/slide
- Full Manual Screen (reduced by 20%):
  - 80 slides @ 10/hr = 6 min/slide
- FOV + Manual Screen:
  - ThinPrep: 4.3 min + 6 min = 10.3 min/slide
  - FocalPoint GS: 5.1 min + 6 min = 11.1 min/slide

**Current Maximum Limits vs. Suggested:**

**Image-Assisted Labs**

<table>
<thead>
<tr>
<th></th>
<th>ThinPrep</th>
<th>FocalPoint GS</th>
<th>Manual Screen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Based on laboratory averages</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individuals will screen more or less</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very little published literature on true F/N rates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>70% labs screening at or below suggested hourly rates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>80% labs screening below suggested daily rates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>70% labs performing &gt;15% full manual review</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial suggestion for future proposal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feedback</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion**

- Current FDA approved limits are too high
  - Reduce to reasonable rate
- Based on 8 hours of screening time
  - Should take into consideration prorated % time of actual screening: 6 – 7 hours
- We should be able to increase productivity at a reasonable rate while maintaining accuracy. Compromising quality to attain high screening goals is unacceptable.

**References**

- Laboratory Economics. National survey of anatomic pathology trends: What are the biggest challenges groups will face over the next 5 years. June 2008;46.
Current Issues in Cytology

10:00 AM
- Andrew Renshaw, MD
- Marshal Austin, MD, PhD
- Tarik Elsheikh, MD

- Optimal quality measures for assessing CT performance:
- Summary
- Questions/Discussion

Improving QA in Gynecologic Cytology

Dr. Andrew Renshaw
Baptist Hospital
Miami, FL

Special thanks to:
Manon Auger, MD
Tarik M. Elsheikh, MD

How do you define quality?

TRUST

- What QA data do you need to trust a lab enough to only get a diagnosis and the QA data on your loved ones Pap?
- I need clinically relevant:
  - Sensitivity
  - Specificity
  - Precision (reproducibility)
No one gives me what I need

- Several ways to measure specificity
  - Biopsy fu, HPV + rate

- No one measures
  - Sensitivity
  - Precision

  You can’t treat CTs like machines – you will never know these measures

  need better and more creative QA measures to account for CTs not being machines

Why is this important?
No one else trusts other labs either

- High workload labs
  - Lowest cost (140 slides/day)
  - Best QA data in the world: error rates of <1 in a million

Question of interest

- Either all labs should copy the high workload labs

  or

- There is something wrong with the QA

6 Keys to Improving QA in Gyn Cytology

- 1. Measure CTs not the Lab
- 3. Forget LSIL
- 4. Precision
- 6. Workload

1. Measure CTs

- The sensitivity of the Pap smear rests ONLY in the hands of the CTs

  I don’t care how good the lab is, I care how good the CT who reads my slide is

- CTs vary considerably

- Most labs can not measure FNP, ASC/SIL ratio etc for CTs only lab

3. Forget LSIL

- Really interested in sensitivity for HSIL – but too rare to measure (under-powered)

  ASC or LSIL?

  “LSIL is a more reproducible (RIGHT) and therefore more clinically relevant, and more accurate surrogate for the sensitivity of HSIL than ASC” (WRONG)
The problem with LSIL - clinical relevance

- Clinical: Risk of CIN 2-3 the same for ASC and LSIL (10%)
- One third of all CIN2-3 first detected by an ASC Pap
- The error rate at LSIL is dominated by CIN1 not CIN2

The problem with LSIL - accuracy

- In every laboratory the majority of sensitivity is lost in ASC not LSIL -these are difficult cases not proficiency test cases
- FNR at ASC is more closely correlated with the FNR at HSIL than the FNR at LSIL
- If you use LSIL every mistake becomes ASC
- TIS high speed good at LSIL lousy at ASC and HSIL

Do cytologists employ a double standard?

- ASC is reproducible enough for patients to get treated but not reproducible enough for QA?

There is a reason the commercial labs use LSIL as their threshold

- Errors are rare
- Errors you do find are easy to call ASC
- Can go at high speeds with TIS and not miss LSIL (while missing ASC and HSIL)

4. Precision

- Gyn cytology is not very precise
  - Abnormal rate varies 30% within labs
  - ASC/SIL ratio varies 600% within labs
- Can’t both be as good
- Can’t trust a negative from a CT with a low abnormal and ASC/SIL rate, and vice versa (though the pathologist is supposed to correct this)

Precision

- Improvement
  - LGS
  - Rapid pre-screening
6. Workload

- How do I figure out how fast a CT can go?
  - TIS
  - What to look for
  - Where to look for it

What to look for: Why are they failing?
- As workload increases, the % of slides with manual review goes down and the time spent on each manual review decreases
- Decreased manual review correlates strongly with FNF and ASC and HSIL rates

Don’t look for LSIL: an administrators dream
- Detection of LSIL remains good at high work loads
- Most likely relates to cytologic features
- If only measure LSIL errors, can go as fast as you want

How do I figure out individual workload?
- Days of the week
- AM vs PM
- Control day?

Days of the week
- 4 CTs screening between 50 and 85 slides/day
- 3 of 4 detected significantly less abnormal cases on Monday or Friday

AM vs PM
- 4 CTs screening between 50 and 85 slides/day
- 2 of 4 CTs detected significantly less abnormal cases in the PM vs the AM
- 1 CT detected the same # of abnormal cases, but in the afternoon they were all classified as ASC
Measuring workload

- CTs tire out in the afternoon
- The effects of workload first appear in the afternoon
- The AM can be used as a control for the PM
- CTs who are doing too many cases either start missing cases in the PM, or start classifying them all as ASC

Recommendation #3

- Should measure ASC, abnormal rate for days of week, many CTs should screen less on M and F
- AM PM comparisons are a powerful tool to assess workload in the laboratory

Tantalizing idea

- Most CTs can screen well before they get tired
- More closely regulating workload may significantly improve performance
- CTs are smart: will they adjust? Will we need a control day?

Conclusion

- Evidence based evaluation of quality in the cytology laboratory generates a very different set of QA measures than most laboratories are currently measuring

Recommendations non workload

- Measure clinically relevant values:
  - CTs not lab
  - Errors with ASC not LSIL
- Measure and Improve sensitivity (didn’t talk about this)
  - pre-screening
  - ASC/SIL ratio between 2-2.5
- Improve precision with
  - LGS
  - pre-screening

Recommendations: workload

- CTs should not all be doing the same workload
- Same or less slides in the PM than AM: there are no “afternoon” screeners
- Abnormal rate should go up in the PM
- Less slides on M and F
- Track manual screening % (>2.5 - 3 x abnormal rate?)
“26,000 deaths per year may be said to be due to cancer of the uterus. This rate has remained practically constant during the past 25 years.”

George N. Papanicolaou MD, PhD and Herbert F. Traut MD

Why Does the “Pap Test Highway” Not Seem Scarier to Some Practitioners?

• Most CIN3 lesions do not progress to invasive cervical cancer, even after decades of follow-up. (Lancet Oncol 2008; 9: 425-34)
• Most cervical cancers are preventable with only periodic screening with relatively insensitive conventional smears. (AHCRP 2007)
• Cervical cancer is a rare event in screened populations.
• Lack of continuity in screening and histopathological follow-up along with liability issues often prevent effective quality improvement reviews of Paps from screened women who later develop cervical cancer.
• Very few “abnormal Paps” detectible on QC rescreening contain lesional cells capable of progressing to cervical cancer.
Cervical Cancer Cases per 100,000 women screened ages 15-85
(“Evaluation of Cervical Cytology” 1999)

<table>
<thead>
<tr>
<th>Pap Smear</th>
<th>No Pap screens</th>
<th>Q3 yr screens</th>
<th>Q2 yr screens</th>
<th>Q1 yr screens</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3015</td>
<td>506</td>
<td>305</td>
<td>109</td>
</tr>
<tr>
<td>↓40% FN</td>
<td>322</td>
<td>181</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>↓60% FN</td>
<td>246</td>
<td>132</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>↓90% FN</td>
<td>161</td>
<td>79</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

The Promise of New Cervical Screening Technologies
Acta Cytologica 1998; 178 - 194

- “Increased Detection of Epithelial Cell Abnormalities by Liquid-based Gynecologic Cytology Preparations: A Review of Accumulated Data”
- The “new paradigm” could be some combination of new technology enhancements- liquid-based sampling, computer-assisted screening, and reflex molecular testing.

Liquid-based Cytology Can Be Performed With Sensitivity Equivalent to HPV Testing

- Shanxi Province Cervical Cancer Screening Study of 1936 unscreened Chinese women with 100% biopsy of study patients: Gynecol Oncol 83: 439-444, 2001
- UK LBC vs HPV ARTISTIC Trial: (32 Pap and 4 hour daily screening limits) Lancet Oncol 10: 672–82, 2009

MWH Database

<table>
<thead>
<tr>
<th>Year</th>
<th>Pap tests</th>
<th>HPV tests</th>
<th>Histological data</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>8,120</td>
<td>11,099</td>
<td>18,665</td>
</tr>
<tr>
<td>2006</td>
<td>11,019</td>
<td>18,652</td>
<td>20,711</td>
</tr>
<tr>
<td>2007</td>
<td>13,107</td>
<td>20,150</td>
<td>26,771</td>
</tr>
<tr>
<td>2008</td>
<td>108,654</td>
<td>113,149</td>
<td>12,118</td>
</tr>
</tbody>
</table>

420,934 Pap test results (97.98% TIS-Imaged TPPT)
83,603 hrHPV DNA test results (HC II method)
45,150 data contain biopsies and surgical procedures

How Fast to Screen Computer-Assisted LBC?
The MWH Approach: Concentrate on Difficult and Clinically Consequential Cases, Especially Cervical Cancers in Screened Women
MWH Screening Speed Rates
Suggested by-
Retrospective Reviews of
Difficult Unrecognized Consequential Cases

1) Neoplastic Glandular Cell Groups
2) Hyperchromatic Crowded Groups
3) Hypocellular Abnormal Immature
   Metaplastic Squames

Unrecognized Neoplastic Glandular
Cell groups

Hyperchromatic Crowded Groups
Not Recognized As Neoplastic

Unrecognized Abnormal Immature
Metaplastic Squamous Cells

MWH Pap Test Slides Reviewed Per
Cytotechnologist-Screening Hour
2005-2008

<table>
<thead>
<tr>
<th></th>
<th>Range</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>3.6 – 10.6</td>
<td>6.7</td>
</tr>
<tr>
<td>2006</td>
<td>3.7 – 10.6</td>
<td>7.4</td>
</tr>
<tr>
<td>2007</td>
<td>3.3 – 11.7</td>
<td>7.6</td>
</tr>
<tr>
<td>2008</td>
<td>4.1 – 11.3</td>
<td>7.8</td>
</tr>
</tbody>
</table>
RELATIVE SCREENING TEST SENSITIVITY ≥ ONE YEAR PRIOR TO HISTOPATHOLOGICAL EVALUATIONS
MWH University of Pittsburgh Data (2005-2008)

<table>
<thead>
<tr>
<th>All Tissue Diagnoses</th>
<th>CIN2/3/AIS/CxCa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pap sensitivity (ASCUS+)</td>
<td>96.06% (2,292/2,386)</td>
</tr>
<tr>
<td>HPV sensitivity</td>
<td>95.41% (728/763)</td>
</tr>
<tr>
<td>Pap &amp; HPV sensitivity</td>
<td>99.91% (2,301/2,303)</td>
</tr>
</tbody>
</table>

Factors Influencing Prevalence of HPV in Women with Negative Cytology

- Varying infection rates in geographical regions and local populations.
- Age of populations.
- Effectiveness of screening and treatment programs leading to ablation of lesions associated with persistent HPV infection.
- An objective measure of residual relative risk after cervical screening.

MWH Experience

Factors Influencing Prevalence of HPV in Women with Negative Cytology

- SubSaharan Africa 25.6%
- South America 14.3%
- Asia 8.7%
- Europe 5.2%

(Lancet 366: 991-998, 2005)

MWH Age-Specific HPV DNA Prevalence for 26,558 Negative imaged TPPT

<table>
<thead>
<tr>
<th>Age Groups</th>
<th># HPV Tests</th>
<th>HPV+ # (%)</th>
<th>95% C.I.</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30</td>
<td>1,299</td>
<td>105 (8.1%)</td>
<td>6.3-10.5</td>
<td>1.7x10^-7</td>
</tr>
<tr>
<td>≥30</td>
<td>25,259</td>
<td>490 (1.9%)</td>
<td>1.4-2.4</td>
<td></td>
</tr>
</tbody>
</table>

Recommended QI Measures

- Document mean cytotechnologist time allotted in the laboratory as a whole for evaluation of each screened Pap test as part of q6 month laboratory cytology quality reviews and make this data available on-line to the public.
- Document and monitor HPV detection rates every 6 months for all women 30 and older with negative Pap co-test results.
Recommended QI Measures

- Document all histopathological diagnoses of CIN2/3/AIS/Ca/CxCa with available negative Pap test results in the last 5 years and extend CLIA style retrospective reviews to these Paps.

- Focus staff education on retrospectively detected “questionable cells” preceding histopathological CIN2/3/AIS/Ca diagnoses.

- Document all histopathological diagnoses of CIN2/3/AIS/Ca/CxCa with available HPV test results in the preceding 12 months and compare abnormal / positive Pap and HPV rates over the same time period.

Image Assisted Paps and Productivity

- Current literature on workload is limited
- Extremes in results:
  - no appreciable change to >200% increased productivity
  - No longitudinal studies have evaluated CT screening performance at progressively increasing rates


<table>
<thead>
<tr>
<th></th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>% increase phase 1-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slides/day</td>
<td>79</td>
<td>11.3</td>
<td>87</td>
<td>12.5</td>
</tr>
<tr>
<td>Slides/hr</td>
<td>11.3</td>
<td>87</td>
<td>12.5</td>
<td>118</td>
</tr>
<tr>
<td>Slides/day</td>
<td>118</td>
<td>12.5</td>
<td>87</td>
<td>110</td>
</tr>
<tr>
<td>Slides/hr</td>
<td>12</td>
<td>118</td>
<td>12.5</td>
<td>14.9</td>
</tr>
<tr>
<td>Slides/hr</td>
<td>37</td>
<td>14.9</td>
<td>12.5</td>
<td></td>
</tr>
</tbody>
</table>

- Productivity increased from 87 to 118 slides/day (12 to 16 slides/hr)

How Many are too Many?

Cytotech Workload Limits and Quality Indicators in the Age of Image Assisted Paps

Moderator: Tarik M. Elsheikh, MD
Director of Cytology
Ball Memorial Hospital
Muncie, IN

Increasing CT Workload Above 100 Slides/day Leads to Significant Reduction in Screening Accuracy

- Utilizing TIS, we evaluated the performance of 3 CTs, with variable levels of experience and screening speeds
- Objective: find out how fast can our CTs screen Paps, using TIS, without significantly reducing their accuracy
- Asked CTs to progressively increase their productivity by an average 30%, over 8 weeks


- We emphasized to the CTs, however, that these were productivity expectations, not “quota”
  - i.e. there were no mandatory minimal # of slides required to screen
- Analysis included comparisons of error rates, screening rates, screening times, and % manual review
- Post-study interviews of the CTs were also conducted
### Results

- As workload increased:
  - ↓ % manual review (P < .001)
  - ↓ actual screening time (min/slide)
  - ↓ total abnormals (P < .001), ASC, and HSIL
  - ↑ FNF

---

### CT Post study Interviews

1. How did they achieve and maintain increased productivity/screening speeds?
2. What was most negative about this experience?
3. What was positive about their involvement in the study?
4. Can they routinely perform at these accelerated speeds?

---

### CT Post study Interviews

- Although "quota" were not mandated, the CTs established self-imposed "productivity targets"
  - there is often confusion regarding the difference between maximum workload limits and quotas, i.e. maximum screening limits may be misinterpreted or misused as productivity targets or quotas

---

### CT Post study Interviews

- “Wanted to get in-pace and not lose it”
  - 2/3 CTs used timers
  - Increased their threshold for atypia, and ignored subtle clues that usually triggered a manual review, i.e. reactive signed out as negative
  - Ignored to check for endocervical cells and organisms, if they were absent in FOV

---

### CT Post study Interviews

- They felt that their main task was to screen as many slides as possible, therefore, did not think much about patient care.
  - “It goes against everything we learned in school, regarding responsibility towards patients”
- Felt mentally abused and needed frequent rests
- Did not screen non-GYN specimens, as it interrupted the momentum of Pap screening

---

### CT Post study Interviews

- Did not have time to share difficult cases with fellow CTs
  - one CT showed a difficult case, which took ½ hour, and threw her off for the entire day
  - Screening was so fast, that sometimes they couldn’t tell if yeast was detected on this slide or 2 slides ago
  - They became unfriendly towards their coworkers, and did not want to interact with them
**Elshelkh et al. Cancer Cytopath (In Press)**

- Any positive experience from this study?
  - Found self-comfort zone
  - Learned about about what I can and can’t do

- Can you handle these accelerated rates in our lab?
  - Would quit and move somewhere else (2)
  - Retire (1)

---

**Summary**

- Minimization of the # of false negative cases, coupled with high specificity, are keys to a successful screening program
- Higher screening rates proportionally cancel out the increased sensitivity gained by imaging
- Most studies that reported significant increases in sensitivity, showed only modest gains in productivity

---

**Summary 2**

- Increased speed is accomplished mostly by reduced time reviewing FOV and % of manual review
- It appears that TIS workloads limits should be <100 slides/day
- Additional studies need to evaluate BD FocalPoint workload limits (< 85 slides/day)
- Manual review should be monitored and performed (> 15-20% of imaged cases)
  - Additional studies are needed

---

**Summary 3**

- Workload limits should not be extrapolated to 8 hrs of screening, rather it should take into account screening time plus necessary mini breaks (actual screening 6.5-7 hrs/day)
- Screening limits are just one aspect of a good QA program
- Need to implement more comprehensive and strict quality measures to monitor CT performance

---

**Summary 4**

- Further investigate potential adverse emotional and social effects on CTs pressured to increase their productivity

---

**Summary 5**

“Since screening excessive # of slides may present a danger to the public, perhaps professional societies should pursue this issue with the appropriate governmental agencies”

Cytology benchmarking working group, CMLTO 1997
Questions and Discussion