Pathologist Extenders: Current and Future

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Amy Clayton
Presentation Objectives

- Past and Present Practice Gaps
- What historical solutions have been considered
- “Pathology Extender” roles at Mayo Clinic
  - Why?
  - Our current model (career ladder for cytotechnologists)
  - Financially worthwhile?
- Possible Future models

Pathology Practice Landscape

- Declining Reimbursement
- Pathologist shortage predicted
- Consolidation of Pathology practices/services

Need for innovative practice strategies
  - Cost effective high quality patient care
  - Coverage of remote sites

*Pathology Extenders seem logical approach*
Pathologist Extender Concept is Not New

What practice needs have been filled by lesser paid, qualified laboratory professionals?

• Pathology Assistants (AAPA Bylaws):
  – Management of (accessioning, clinical history review, grossing, photography, and triage of specimens for light microscopy and additional studies) Surgical and Autopsy pathology specimens, Resident teaching and Administrative responsibilities

• Cytotechnologists:
  – Screening Cytology: GYN, Non-GYN, FNAs
  – Sign out: Negative GYN PAPs

Current Pathologist Practice Gaps?

• Soaring need for management of ancillary prognostics, companion diagnostics, regulatory requirements for pre-analytic, analytic and post-analytic practice elements
• Digital Pathology
  – Image analysis, image selection, remote transmission, archive and annotation
• Rapid On-Site Evaluation (ROSE) reimbursement
  – Endoscopic, Bronchoscopic, radiographic, ultrasonic FNA procedures
  
  Many practices are sacrificing 88132 reimbursement because it’s not cost effective to send pathologist to procedure
• Screening assistance on high volume specimens that require intense focus and orientation to detail
  – Microorganisms, prostate biopsies, ECC, Cervical cone
• Other?

*Engaged Forbes Group to analyze profession*

- Defined cytology profession as “unique body of knowledge” that fills an existing or emerging market gap
- ..there is economic justification...for a more highly skilled cytology profession
- Predicts clinician and pathologist shortage...requires new systems

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*Forbes Group:*

- Health consumerism ...changing laboratory industry....demanding more cost effective testing
- Expanding scope of cytologists ....could prove essential to increasing productivity and efficiency of cytopathology
- Digital image management important- do cytopathology labs want to be at table or let radiology do it?
Future of Cytology Summit
American Society of Cytopathology
annual meeting, 2009

• Proposed Strategies:
  1. Do Nothing (let the profession evolve)
  2. Optimize the current scope of practice
     • without additional formal education
     • “on the job training”
  3. Expand Cytotech role with novel educational tools (Career ladder)
     • Master’s degree
     • Combine with CLS programs
     • Combine with Pathology Assistant programs
  4. Create a new Cytotechnologist Professional position:
     “Cytopathology Assistant”

What are individual practices doing?

Share our (Mayo) journey...

2000- 2014
Our Own Transformation

Mayo Clinic Practice Needs:
• Pathologist Shortage in our group
• Increasing workload
• ACGME resident requirements limited practice coverage needs
• Innovation to improve Cytology Testing
  – FISH on cytology specimens (biliary brush, bronchial brush)
  – Ploidy analysis
  – Need more from less (testing on smaller specimens)
• Exploding need for histologic tumor ID and workflow management for molecular genetic testing
• Improved quality desired for quantitative IHC analysis (ER/PR/HER2)

Expanded Pathology Assistant Roles
• Complete autopsies: record review, dissection, PAD, histologic review and FAD (final sign-out by pathologist).
• Death Scene Investigation (including mass fatality planning, infant mortality review, cremation approval)
• Coding
• Tissue procurement for research
• Gross and Microscopic synoptic template development
• Mock up death certificates (D/C) for pathologists
• Training and competencies for Histotechnologists
• Supervisory role (to include personnel management) in Frozen Section and Routine Gross Laboratories
Expanded Cytotechnologist Roles

• *Unique skills* of the cytotechnologist
  • Excellent microscopic morphology skills
  • Well developed understanding of neoplasia concepts (reactive atypia, hyperplasia, in situ/invasive neoplasia)

• Developed cytotechnology curriculum that supports the expanded cytotechnology roles

It’s still about the cells!
Mayo Cytotechnologist Responsibilities

2000

- GYN
- Non-GYN
- EUS FNA
  - On site adequacy
- Digital Image Analysis
  - Ploidy and Proliferation

2014

- FISH Analysis
- FNA Screening
- ER/PR and Her2 quantitation
  - Manual
  - Digital image analysis
- Circulating Tumor Cells
- AFB Screens
- Test Development
- *Workflow Management Support
  - Molecular Testing
  - Specimen problem solving

Circulating Tumor Cell Analysis
• Acid Fast Bacillus stain - prescreening for pathologists

For 2011: approximately 200 cases per month

Multidisciplinary Workflow Facilitators:
Clinician to AP to Molecular Lab
Ancillary Prognostic/Theragnostic testing requests

• Pre-analytic
  – Test utilization (is order appropriate?)
  – Specimen adequacy
  – Block selection
  – Post histology tissue review (tumor percent)
  – Facilitate transfer to molecular lab for testing

• Analytic
• Post Analytic
  – Integrated reports (HER2, ER, PR, MIB)

Future expanded need with molecular testing?
Additional Roles of Cytotechnologists

Test Volumes - New Cytotechnologist Roles

Cytotechnologist Career Ladder
Distribution of Cytotechnologists in Expanded Roles

Financial Impact:
Cytotech Time VS Pathologist Time

Labor Cost Per Test
A Cost Effective Approach

<table>
<thead>
<tr>
<th>Test</th>
<th>Path Analysis Time Reduction</th>
<th>Expense Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>FISH</td>
<td>96%</td>
<td>71%</td>
</tr>
<tr>
<td>Breast IHC</td>
<td>86%</td>
<td>67%</td>
</tr>
<tr>
<td>CTC</td>
<td>71%</td>
<td>41%</td>
</tr>
</tbody>
</table>

Cytotechnologist Responsibilities
FISH Testing

Cytotechnologist FISH Workflow

43 minutes per case

- Match Paperwork and Slides
- FISH Analysis
- Capture Images for Permanent File
- Enter FISH Interpretation into LIS
Pathologist Responsibilities
FISH Testing

**Pathologist FISH Workflow**

- Review Signal Patterns
- Review Representative Images
- Review Patient Clinical Information
- Verify/Release Report in LIS

2 minutes per case

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**FISH Process Cost Analysis**

<table>
<thead>
<tr>
<th></th>
<th>CT time (min)</th>
<th>Pathologist Time (min)</th>
<th>N per year</th>
<th>Salary Cost*</th>
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</thead>
<tbody>
<tr>
<td>With CT analysis</td>
<td>43</td>
<td>2</td>
<td>6099</td>
<td>$149,904</td>
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<tr>
<td>Without CT analysis</td>
<td>38</td>
<td>6099</td>
<td></td>
<td>$531,127</td>
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</table>

**Savings**

$375,598

**CT Responsibilities: IHC-ER, PR, HER 2**

**IHC Workflow**

- Match paperwork with slides
- Check paperwork for fixation times
- Verify invasive versus in situ cancer
- Perform IHC quantification – manual and image analysis
- Enter interpretation into LIS
- Enter methodology, fixation, and controls comments

**18 minutes per case**

**Pathologist Responsibilities: IHC-ER, PR, HER 2**

**Pathologist Workflow**

- Review H&E Slides and Verify Tumor
- Review IHC Slides – Verify IHC Score
- Verify /Release Final Report in LIS

**3 minutes per case**
### IHC- ER, PR, HER 2 Analysis

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<th>N: per year</th>
<th>Salary Cost*</th>
</tr>
</thead>
<tbody>
<tr>
<td>With CT analysis</td>
<td>18</td>
<td>3</td>
<td>6000</td>
<td>$91,500</td>
</tr>
<tr>
<td>Without CT analysis</td>
<td>20</td>
<td>6000</td>
<td>$274,980</td>
<td></td>
</tr>
</tbody>
</table>

Savings: $183,480


### What Makes Sense for Our Practice?

- Use Cytotechnologists in Expanded Roles
  - Provide cost effective service
  - Reduce burden on Pathologists
  - Preserve the field of cytotechnology
    - *in effect preserving the application of morphologic assessment on numerous aspects of laboratory testing*
  - Enhance satisfaction for cytotechnologists
Mayo Pathology Laboratories: What have we done?

- Expanded Cytotechnologist Role? Yes
- Changed Pathologist-Cytotechnologist Relationship?
  - Still work as team
  - New group of pathologists to work with: Surgical Pathologists, Molecular Pathologists
- Created Visibility for Cytotechnologists in Department/Institution? Yes
  - Impact on resource allocation? YES!

Mayo Cytology Laboratories: What have we NOT done?

- We have not worked outside the current regulatory environment
  - No change in CPT codes/billing
  - Pathologist does final review on all activities
- Cytotechnologist as an Independent Practitioner
  - Much bigger than our single practice can change
Future of Cytology Summit
American Society of Cytopathology
annual meeting, 2009

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  – Create a new Cytotechnologist Professional position:
    “Cytopathology Assistant”
    or
    (Advanced Morphology Practitioner)

What Gaps are Still Left to Fill?
• Microscopic review of high volume biopsy/surgical specimens (prostate, GYN, Lymph node dissection)
• Triage/preorder IHC on selected case types
• Clinical Liaison
  – Test utilization, report queries, specimen submission queries
• Digital Pathology needs
• Integrated Reporting
  – Molecular/Ancillary Prognostic results
• ROSE (billable by “advanced practitioner”)
• Sign-out of “Negative” Non-GYN cytology (billable)
Is it time for: “Advanced Morphology Practitioner”?

- Are we doing things in our practice that can be better managed by additional pathologist extender activities?
  
  "Allowing pathologists to focus efforts on more cost effective practice activities"
  
  - Pathology assistant role (gross, staging, autopsy, education) is well established, but more opportunities exist
  
  - Advanced morphology practitioner role is evolving
    
    - Cost effective in our practice model
    - Can that be applied more broadly to encompass independent review?
    
    - Predicated on knowing when to escalate to pathologist (no different than NP/PA model)
    
    - What Educational Curriculum would support?

Advanced Morphology Practitioner Model A (Mayo Model)

Pathologist

Bill for services as currently done

Advanced Morphology Practitioner
Advanced Morphology Practitioner
Model B (Physician Assistant)

Pathologist

Bill for services as currently done

Advanced Morphology Practitioner

Bill independently for selected services

The Time is Right for Innovative Practice Strategies

Requires Bold Leadership
Focus on Value Based Patient Care
Collaborative Spirit