Learning Objectives

- To learn how different methods of slide review may be used to improve practice quality
- To learn causes of error detected by slide review
- To learn strengths and limitations of different review methods

Agenda

- Error
- Methods of error detection
- Secondary review processes
- Data from 5% and focused review studies
- Using secondary review data for improvement

Accuracy and Precision

Discrepancy Detection

- Proportion of discrepancy depends on detection method
  - Retrospective review
    - Correlation (e.g., cytologic-histologic)
    - Random 5% of all cases
    - Focused on specific cases
  - Prospective review
    - Challenging case review
    - Double viewing
Error Root Cause

- Total testing process: pre-pre-analytic, pre-analytic, analytic, post-analytic, post-post-analytic
    - Error rate 20%
    - 17% in pre-pre and post-post phases
    - 0.2% analytic phase

Error Root Cause

- Eindhoven Classification Model for the Medical Event Reporting System for Transfusion Medicine
  - Latent: technical, organizational
  - Active: knowledge, rules, skills
- Over 95% of diagnostic errors are associated with a system failure

Use of Secondary Review

- Often used as a quality assurance tool
- Secondary review processes are costly
- Difficult to use error data for improvement
  - Lack of formal root cause analysis
  - Lack of ability to change processes
  - Lack of study of implementation science

Random Versus Focused Review

- Subspecialty based sign out practice
- Error defined as a difference in primary and review diagnosis (i.e., at least one diagnosis does not correlate with disease process)
- Assess error detection proportion and harm
- Adjudicative process through committee

Random Review

- January 1, 2001 – December 31, 2005
- Used laboratory information system to identify 5% of cases (additional cases added for absent cases or gross only cases)
- Cases circulated to all pathologists
- Adjudicated if diagnosis was incorrect and secondary to interpretation
- Classified error into: 1) major and 2) minor severity categories based on subjective (no formally obtained outcome data) assessments

Focused Review

- January 1, 2006 – December 31, 2006
- Subspecialty directors chose area (e.g., higher levels of diagnostic uncertainty or perceived lack of terminology standardization)
- Performed by one or several pathologists in specific subspecialty
- Adjudicated error and subjectively assessed severity

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Comparison

- Compared pseudo-random 5% and focused review error proportions
- Performed formal outcome analysis
  - Outcome classified as
    - No harm
    - Near miss
    - Harm (minimal, mild, moderate, and severe)

Discrepancy Proportion

<table>
<thead>
<tr>
<th>Method</th>
<th>Total cases</th>
<th>Cases reviewed</th>
<th>Major errors</th>
<th>Total errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>213,142</td>
<td>7,444</td>
<td>27</td>
<td>195</td>
</tr>
<tr>
<td></td>
<td>(3.5)</td>
<td>(0.36%)</td>
<td>(2.6%)</td>
<td></td>
</tr>
<tr>
<td>Focused</td>
<td>54,663</td>
<td>380</td>
<td>12</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>(0.70)</td>
<td>(3.2%)</td>
<td>(13.2%)</td>
<td></td>
</tr>
</tbody>
</table>

Examples of Errors Detected by 5% Review

<table>
<thead>
<tr>
<th>Site</th>
<th>Original diagnosis</th>
<th>Review diagnosis</th>
<th>Comment</th>
<th>Error severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stomach</td>
<td>No abnormality</td>
<td>Chronic inactive gastritis</td>
<td>&gt; 6 months delay in diagnosis</td>
<td>Mild</td>
</tr>
<tr>
<td>Bladder</td>
<td>Blood clot</td>
<td>Blood clot with tumor</td>
<td>Return for second biopsy</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

Examples of Errors Detected by Focused Review

<table>
<thead>
<tr>
<th>Site</th>
<th>Original diagnosis</th>
<th>Review diagnosis</th>
<th>Comment</th>
<th>Error severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colon</td>
<td>Adenocarcinoma in colectomy (0/20 nodes +)</td>
<td>1/20 nodes +; CT scan follow-up normal</td>
<td>Minimal</td>
<td></td>
</tr>
<tr>
<td>Colon</td>
<td>Adenocarcinoma in colectomy (4/18 nodes +)</td>
<td>1/18 nodes +; stage N1</td>
<td>No recurrence</td>
<td>Minimal</td>
</tr>
<tr>
<td>Colon</td>
<td>Adenocarcinoma in colectomy (1/17 nodes +)</td>
<td>0/17 nodes +; PET scan no evidence of metastasis</td>
<td>Minimal</td>
<td></td>
</tr>
</tbody>
</table>

Findings

- Statistically significant higher proportion of errors detected by focused review ($P < 0.001$)
- For focused review subspecialty, the number of major errors ranged from 0% to 5.7% of cases reviewed
- Harm:
  - 5% process: 12 cases of major errors (44.4%); 2 cases moderate or above
  - Focused: 7 cases of major errors (58.3%); 0 cases moderate or above

Root Cause Analysis

- 5% review: errors secondary to a variety or causes (e.g., cognitive, poor quality specimen, lack of standardization, lack of uniform expertise)
- Focused review: errors generally secondary to lack of diagnostic standardization among pathologists
Standardization

- Diagnostic criteria for well differentiated liposarcoma
- Diagnostic criteria for metastatic adenocarcinoma in a lymph node
- Diagnostic criteria for high grade dysplasia
- Diagnostic criteria for ASAP

Summary

- Benefits of 5% review:
  - All pathologists participate
  - Pathologists see a variety of specimen types
  - Greater percentage of errors associated with moderate+ harm detected (compared to focused review)
  - Less work in review design

Summary

- Benefits of focused review:
  - Subspecialty areas focus on lack of standardization or other problems
  - Higher percentage or errors (and major errors) detected
  - Significantly lower number of slides evaluated
  - Errors detected in context of a specific problem
  - Greater ability to create standardizing procedures

References


Thank you for participating!
Barcoding for Specimen Identity
Rodney Schmidt, MD, PhD

Learning Objectives
• Discriminate between the different types of barcoding applications.
• Explain how thoughtful barcoding applications improve both quality and efficiency in anatomic pathology.
• Define how to justify a barcoding project in financial terms.

Agenda
• Reasons to bar-code
• Importance of workflow
• Gross room benefits
• Slide tracking benefits
• Benefits in financial terms

Imperatives

Why barcode?
• Error reduction and patient safety
  – Errors labeling things
• Reduced medical-legal liability
• Custodial responsibility & inventory control
• Efficiency reasons
  – Helps you do your job faster
  – Reduced time wasted on error resolution
  – Indirect efficiencies because of better knowledge about where things are

Disclosure
• Bar-coding software developed at UW (OmniTrax and OmniImage) has been licensed by UW to Pathway Pathology Consultants for relicensing to end-users.
• Dr. Schmidt has a speaking/consulting relationship with Thermo-Fisher.
• No other financial relationships with hardware or software manufacturers.
**Manual vs Bar Codes**

- A well-trained data entry operator makes a data entry error once every 300 keystrokes.
- Scanning a Datamatrix 2D bar code produces 1 error in 10.5 million (worst case) and 1 error in 612.9 million (best case).

---

**Achievable Error Rates**

<table>
<thead>
<tr>
<th>Error rates</th>
<th>Error Prevention Methods</th>
<th>Real world Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/100</td>
<td>Clear process</td>
<td>Errors filling out lab requisition</td>
</tr>
<tr>
<td></td>
<td>Reliance on education/vigilance</td>
<td>Failure to give results to patients</td>
</tr>
<tr>
<td>1/1,000</td>
<td>Clear process</td>
<td>Mislabeled specimens</td>
</tr>
<tr>
<td></td>
<td>Systems for error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>identification and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mitigation</td>
<td></td>
</tr>
<tr>
<td>1/10,000</td>
<td>Advanced design +</td>
<td>Specimen loss</td>
</tr>
<tr>
<td></td>
<td>Automation</td>
<td>Computer interface errors</td>
</tr>
<tr>
<td>1/100,000</td>
<td>Error ID/</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mitigation</td>
<td></td>
</tr>
</tbody>
</table>

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**Computing and Workflow**

"Adding technology to a process always makes the process less efficient."
- Charles P. Friedman

You have to change the process to take advantage of the technology in order to realize the benefits.

---

**What is Bar-coding?**

- **Labeling**
  - Putting barcodes on things
  - Technically easy, cheap (some methods)
- **Tracking**
  - Location updates; inventory control
  - Added work; needs software; modest cost
- **Driving**
  - Using barcodes to expedite workflow
  - Disruptive technology; expensive; LIS interoperability

---

**Bringing Bar-coding to AP**

- Track slides (2005)
  - Eliminate the "lost slide" problem
  - Ease conference prep
- Specimen labels (2006)
  - Tissue discards and tracking
  - Drive gross photography
- Block creation and labeling (2008)
  - Automated JIT production of barcoded
  - Gross room QA process and tracking
- Slide creation and labeling (2008)
  - Automated JIT creation of barcoded slides
  - Facilitate workflow and QA
- Eliminate all manual labeling (and errors)
- Facilitate workflow – JIT information display

---

**Material identification (2004)**

- Handwritten specimen labels
- Manual, off-line cassette labeling
- Hand-written slide labels
Primary labeling errors

<table>
<thead>
<tr>
<th>Blocks</th>
<th>Slides</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>60</td>
<td>80</td>
</tr>
<tr>
<td>80</td>
<td>100</td>
</tr>
<tr>
<td>100</td>
<td>200</td>
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<td>700</td>
<td>800</td>
</tr>
<tr>
<td>800</td>
<td>900</td>
</tr>
<tr>
<td>900</td>
<td>1000</td>
</tr>
</tbody>
</table>

Accession number is re-entered into a standalone cassette imprinter.

Targets – Gross Room

- Foolproof labeling
  - No human labeling/data entry
- Reduced dependence on support staff
  - Off-hours availability
  - Redirection of support personnel
- Reduced waste of cassettes
- Grossing step at least as fast as current

The unsupervised Resident!

Accesion and Label

Receive specimen and enter data into the LIS

Generate a bar coded label for the specimen and laboratory request form.

Just-in-Time Printing

Fewer handling steps
Fewer (1) error opportunities
Fewer QA processes

Q&E Benefits

<table>
<thead>
<tr>
<th></th>
<th>&quot;Classic&quot;</th>
<th>&quot;Just-in-Time&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling steps</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Error opportunities</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Manual QA steps</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Cassette wastage</td>
<td>25/t (~7%)</td>
<td>0</td>
</tr>
<tr>
<td>Primary labeling errors</td>
<td>988/yr (est.); 1.2%</td>
<td>2 in 3 mo (initial); 0 in next 7 mo; 0.003%</td>
</tr>
<tr>
<td>Grossing efficiency</td>
<td>--</td>
<td>At least as fast</td>
</tr>
<tr>
<td>Support staff</td>
<td>--</td>
<td>0.75+ FTE</td>
</tr>
</tbody>
</table>

Accession and Labeling

Accession specimens
Label specimens
Label cassettes
Group with specimens
Move to staging area
Move to gross bench
Lay-out cassettes
Fill cassettes
Request more cassettes
Reconcile with LIS
Transport for processing
Store excess with specs

QA Steps

Accesion specimens
Bar-code specimens
Scan/print cassettes
Rack filled cassettes
Fill cassettes
Lay out cassettes
Move to gross bench
Group with specimens
Label cassettes
Store excess with specs

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Benefits

- **Efficiency**
  - No manual pre-printing and sorting of cassettes
  - Quick just-in-time additional cassettes
  - Default cassettes from PowerPath specimen panels
  - Blocks automatically ordered in PowerPath

- **Quality**
  - No manual labeling (no errors)
  - Scanning specimen barcode assures correct specimen
  - Records which blocks are sent for processing

Histology – Embedding

- **Target**
  - View critical information about block and specimen
  - Efficient workflow

- **Block scan**
  - Embedding instructions
  - Number of pieces of tissue
  - Specimen info
  - (Record timestamps)

Histology – Cutting

- **Targets**
  - Present critical information (block, specimen)
  - Eliminate manual slide labeling
  - Block/slide verification

- **Block scan**
  - JIT slide auto-labeling
  - Info display

- **Slide scan**
  - Block/slide match

Cutting - Benefits

- Elimination of hand labeling
- Much faster than manual labeling for blocks with many slides
- Fewer block/slide mismatches

Slide Tracking Workflow

- Histology work order completes with scanning
- Pull for conference
- Sendouts
- Pathology Offices
- Faculty signout
- Resident review
- Deliver
- Ship
- File
- Histology

Slides – Benefits

- Less staff time looking for slides
- Faster to find last location than make a phone call
- Fewer arguments over whether slides were delivered
- Fewer recuts?
- Improved job satisfaction
  - **Saved me 30 min the first day!**
- **Overall savings > 2.0 FTE!**
**Slides Benefits**

**FTE Savings**

| Histology | +0.5 FTE | Reduced time hunting for mis-delivered slides |
| Office staff | +5.1 FTE | Auto completion of outstanding orders when slide is scanned |
| Office staff | +0.25 FTE | Reduced time for conference preparation |
| Office staff | +0.5 FTE | Increased efficiency regarding send outs |

**Barcoding Benefits**

- Direct personnel (FTE)
  - 2.0 Slide delivery and tracking
  - 0.75 Cassette printing
  - 0.1 Specimen discards
  - 0.1 Document scanning
  - TBD Fluorescence image import

- Error Reduction
  - Elimination of all manual labeling steps!
  - Reduced labeling errors
    - Specimens
    - Blocks
      - ~988/yr to essentially 0
    - Slides
    - Gross photos
    - Scanned documents
    - Photomicrographs

- ~$150,000/yr assuming $50,000/FTE

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**Conclusions**

Bar-coding automation

- More than just tracking — disruptive technology!
  Workflow must change.
- Allows processing of increased workloads with static FTE levels
- Improves patient safety
- Fiscally justified

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Learning Objectives/Disclosure

- Define amended reports
- Classify types of amended reports
- Illustrate amended report monitoring

No commercial interest in amended reports

To Evaluate and Improve:

- Characterize amendments
- Relate frequencies & fractions to process
- Monitor process changes to test how frequencies & fractions change

Topics For Discussion

- How should addenda vs. amendments be sorted?
- Do amendments mean something regarding quality vs. safety?
- How should ‘old cases’ be handled when errors are discovered?

Diagnostic Anatomic Pathology

- Turns tissues and cells into information
- Records information from specimens in reports
- Reveals loss of information, addition of misinformation in amended reports
**Amendments: Definition**

- Changes in information
- Not additions to information
- After, not before release*

*Release = ‘signing out’, publication

---

**Indices of Anatomic Pathology Process Defects**

- Sources of confusion ("noise")
- Causes of distrust (among "receivers" of "signal")
- Instances of rework (producing otherwise unnecessary "retransmissions" of "signal")
- Suggestions of distribution of unwanted variation ("noise") in pathology process ("system")

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**Potential Utility of Amended Report Monitoring**

- Observes a system-wide domain: Reports
- Permits consistent classification: Taxonomy
- Generates defect rates and fractions: Quantification
- Assesses interventions: Process change

---

**Problem of Non-Standard Terms For Altered Reports**

- Addendum
- Addition
- Amendment
- Correction
- Revision
- Supplement

---

**Standard Terminology**

- **Amendment**: All changes that do not only add information
- **Addendum**: Only changes that just add information
- All other terms removed from use

---

**Taxonomy Development**

- Review of derivation set: 141 changed reports
- Division of changed reports into four categories:
  - misinterpretations
  - misidentifications,
  - specimen defects
  - report defects
- Application of categories to training set: 131 changed reports
Categorical Imperatives

- Classification of each defect in one-and-only one category
- Agreement of (4) independent observers on each defect’s class
- Revision of study definitions
- Application of revised categories to validation set: 430 changed reports
- Assessment of classifier agreement using kappa statistic
- Comparison of classifier agreement within vs. among institutions

Inter-institution Comparison

- Thirty unselected amendments (15 HFH; 15 UPMC Shadyside)
- Circulated among seven practices (3 in NE, 1 in SE, 3 in MW)
- Agreement among classifiers measured using kappa statistic

Taxonomic Agreement

<table>
<thead>
<tr>
<th>Cases</th>
<th>Reviewers</th>
<th>Median Kappa</th>
<th>Kappa Range</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>430</td>
<td>4</td>
<td>0.8780</td>
<td>0.8416-0.9144</td>
<td>excellent</td>
</tr>
<tr>
<td>30</td>
<td>7</td>
<td>0.6235</td>
<td>0.3105-0.8975</td>
<td>very good</td>
</tr>
</tbody>
</table>

Quality Measures

- Amendment Rates: Annual number of amendments per annual reported cases
- Error Fractions*: Misinterpretation, mis-ID, specimen defects, report defects
  *Changes measured by Pierson test

Stratifying Variables

- Defect Discoverer: Pathologist, clinician, other staff, unknown.
- Mechanism of Discovery: Clinician call, conference review, pathology review, other.

Four Defect Categories

- Misinterpretations (Mis-IP)
- Misidentifications (Mis-ID)
- Specimen Defect (SD)
- Report Defect (RD)
Misinterpretation: Three Subtypes

- Added Misinformation: False positives; over calls
- Missed, lost Information: False negatives; under calls
- Misclassified Information: Confusion of similar ‘weight’ categories

Misinterpretation: Two Levels

- Primary Level: Changes between positive/negative; benign/malignant
- Secondary Level: Changes in grade, stage, margin(s), node status

Misidentification

- Patient
- Tissue
- Laterality
- Anatomic Localization

Specimen Defects

- Lost
- Inadequate size, volume
- Absent, discrepant measurement
- Inadequate representation
- Absent, inappropriate ancillary studies

Report Defects*

- Missing, erroneous non-diagnostic information (practitioner, procedure, date, codes)
- Dictation, transcription slips (typographical errors in strict sense)
- Failures or aberrations of e-formats, e-transmissions

*Report defect category is considered only after other three categories are definitely excluded

Range of Amended Report Rates Against Which Taxonomy Developed

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year One</td>
<td>2.8/1000</td>
</tr>
<tr>
<td>Year Two</td>
<td>2.6/1000</td>
</tr>
<tr>
<td>Year Three</td>
<td>3.4/1000</td>
</tr>
<tr>
<td>Year Four</td>
<td>4.8/1000</td>
</tr>
</tbody>
</table>

Amended report rates rise with real time monitoring
Amended Report Defect Types During Taxonomy Development

<table>
<thead>
<tr>
<th>Defect Type</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misinterpretation</td>
<td>Steady fraction</td>
</tr>
<tr>
<td></td>
<td>23%-29% of defects</td>
</tr>
<tr>
<td>Mis-ID and Report Defects</td>
<td>Linked fractions:</td>
</tr>
<tr>
<td></td>
<td>Mis-ID fell as RD's rose*</td>
</tr>
<tr>
<td>Specimen Defects</td>
<td>‘Ping-pong’ pattern:</td>
</tr>
<tr>
<td></td>
<td>4-10% of defects</td>
</tr>
</tbody>
</table>

*Hypothesis: Increased attention simultaneously caught more pre-publication mis-IDs more post-publication RDs

Taxonomy Development Final Year ['Baseline']

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of Case Reports</td>
<td>46,468</td>
</tr>
<tr>
<td>Total Amendments</td>
<td>225</td>
</tr>
<tr>
<td>Amendment Rate</td>
<td>4.8/1000</td>
</tr>
<tr>
<td>Misinterpretations</td>
<td>53 (24%)</td>
</tr>
<tr>
<td>Mis-IDs</td>
<td>44 (19%)</td>
</tr>
<tr>
<td>Specimen Defects</td>
<td>20 (9%)</td>
</tr>
<tr>
<td>Report Defects</td>
<td>108 (48%)</td>
</tr>
</tbody>
</table>

Stratifying Variables - ‘Baseline’

<table>
<thead>
<tr>
<th>Category</th>
<th>Defect Discovers</th>
<th>Pathologists</th>
<th>Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misinterpretations</td>
<td>(74%)</td>
<td></td>
<td>(66%)</td>
</tr>
<tr>
<td>Plurality of report</td>
<td>(44%)</td>
<td></td>
<td>(66%)</td>
</tr>
<tr>
<td>Most misinterpretations</td>
<td>(83%)</td>
<td></td>
<td>(66%)</td>
</tr>
</tbody>
</table>

Discovery Mechanism

<table>
<thead>
<tr>
<th>Category</th>
<th>Most misinterpretations (83%)</th>
<th>Most misidentifications (66%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conference Review</td>
<td>Most misinterpretations (83%)</td>
<td>Most misidentifications (66%)</td>
</tr>
<tr>
<td>Clinician Calls</td>
<td>Most misinterpretations (83%)</td>
<td>Most misidentifications (66%)</td>
</tr>
</tbody>
</table>

‘Sands of Pathology’*

Taxonomy’s intra institutional agreement ‘excellent’; inter institutional agreement ‘good’

Taxonomy must be consistently applied to provide comparable results among sites (and their components) over time.

* A pearl forms around a nidus of irritating sand

A Gram of Sand (or Salt): The Need For An Independent Editor Using Objective Criteria

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self serving addenda</td>
<td>&quot;Benign prostate tissue&quot; to &quot;prostatic adenocarcinoma&quot;</td>
</tr>
<tr>
<td>Misapplied Criteria</td>
<td>&quot;Intradermal nevus&quot; to &quot;eccrine poroma&quot; specimen mis-ID not report defect</td>
</tr>
<tr>
<td>Failure to Find Root Cause</td>
<td>&quot;Mild dysplasia CIN1&quot; to &quot;Focal severe dyspl. CIN3&quot; not false negative (undercall) but inadequate sampling (specimen defect)</td>
</tr>
</tbody>
</table>

Contrast of ‘Baseline Rates’

<table>
<thead>
<tr>
<th>Monitoring Type</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive Monitoring</td>
<td>2.8/1000</td>
</tr>
<tr>
<td>Active Monitoring</td>
<td>4.8/1000</td>
</tr>
</tbody>
</table>
Importance of Conference Reviews

- Detected 10% - 20% of all defects requiring amendment at baseline
- Discovered 50% of mis-interpretations during passive monitoring, 80% of mis-interpretations during active monitoring

Domain: Surgical Pathology Process

- Patient and specimen identification
- Specimen handling
- Diagnostic interpretation
- Result reporting

Measures: Applying Taxonomy

- Total amendments
- Amendments per thousand cases
- Amendment fractions by defect type

Events During Monitoring

- Pathologist production of reports’04
- Amendment process editing began ’05
- Production System introduced ’06
- HFPS fully operational ‘07

Monitoring Results 1: Defect Rates

<table>
<thead>
<tr>
<th>Year</th>
<th>Amendments</th>
<th>Cases</th>
<th>Amendments/1000 Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>225</td>
<td>46,468</td>
<td>4.8</td>
</tr>
<tr>
<td>2005</td>
<td>475</td>
<td>46,880</td>
<td>10.1</td>
</tr>
<tr>
<td>2006</td>
<td>374</td>
<td>48,010</td>
<td>7.8</td>
</tr>
<tr>
<td>2007</td>
<td>306</td>
<td>48,422</td>
<td>6.3</td>
</tr>
</tbody>
</table>

Observations: Defect Rates

- Introducing edit function doubled defect detection
- Defects fell one-fifth with HFPS introduction
- They fell another 15% with full implementation
Results II: Monitoring Defect Fractions

<table>
<thead>
<tr>
<th>Year</th>
<th>Misinterp</th>
<th>MisIDs</th>
<th>Spec. Defects</th>
<th>Rep. Defect</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>53(23.5%)</td>
<td>44(19.5)</td>
<td>20(9.0)</td>
<td>108(48)</td>
</tr>
<tr>
<td>2005</td>
<td>87(18.3%)</td>
<td>74(15.6)</td>
<td>9(1.9)</td>
<td>305(64.2)</td>
</tr>
<tr>
<td>2006</td>
<td>59(15.8%)</td>
<td>46(12.3)</td>
<td>16(4.3)</td>
<td>253(67.6)</td>
</tr>
<tr>
<td>2007</td>
<td>22(7.0%)</td>
<td>38(12.0)</td>
<td>33(11.0)</td>
<td>213(70.0)</td>
</tr>
</tbody>
</table>

Observations: Defect Fractions

- Mis-interpretation fraction fell during monitoring
- Fall steeper after HFPS’s full implementation
- Mis ID fraction fell in first 2 years, then leveled off
- Specimen defects produced few amendments
- Report defects fraction were largest, varied most, increased most

Amended Report Monitoring: Ongoing LEAN Interventions ’06–’08

<table>
<thead>
<tr>
<th>Measures</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification defects</td>
<td>Goal-directed clinician education</td>
</tr>
<tr>
<td>Specimen defects</td>
<td>Redesign of specimen accession</td>
</tr>
<tr>
<td>Interpretation defects</td>
<td>Double reading- breast, prostate*</td>
</tr>
<tr>
<td></td>
<td>*2% of cases: ~800/47,500</td>
</tr>
</tbody>
</table>

Monitoring Amendments ’06–’08

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Amendments</td>
<td>374</td>
<td>306</td>
<td>271</td>
</tr>
<tr>
<td>Amendments per 1000 reports</td>
<td>7.8</td>
<td>6.3</td>
<td>5.5</td>
</tr>
</tbody>
</table>

Fractions of Amendment Subtypes

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misinterpretations</td>
<td>16%</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>Misidentifications</td>
<td>12%</td>
<td>12%</td>
<td>9%</td>
</tr>
<tr>
<td>Specimen defects</td>
<td>4%</td>
<td>11%</td>
<td>4%</td>
</tr>
<tr>
<td>Report Defects</td>
<td>68%</td>
<td>70%</td>
<td>84%</td>
</tr>
</tbody>
</table>

Observations On Interventions

- Focused double-review of a small fraction of cases associated with fall in misinterpretations*
- Goal directed clinician education on specimen ID had only modest impact on mis-ID
- Accession re-design associated with increase, then decrease in specimen defect fraction

* "Undetected confounding factors cannot be excluded in real practice"
Take Home Messages From On-Going Monitoring

- Pathologist “finalling” increases report defects
- Editing (introducing systematic classification) increases defect detection
- LEAN initiative (HFPS) reduced defects
- HFPS influence grew with ongoing, widening integration into practice

Interpretation, Identification, Specimen Defects ’07-’09

- Less frequent (16%)  
- More worrisome

Interpretation Defects ’07-’09

<table>
<thead>
<tr>
<th></th>
<th>Year A [’07-’08]</th>
<th>Year B [’08-’09]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amendment rate</td>
<td>7.1/1000</td>
<td>4.8/1000</td>
</tr>
<tr>
<td>Primary Dx</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Secondary Dx</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Reclassification</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>11</td>
</tr>
</tbody>
</table>

Identification Defects ’07-’09

<table>
<thead>
<tr>
<th></th>
<th>Year A [’07-’08]</th>
<th>Year B [’08-’08]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Anatomic site</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Laterality</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Tissue</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>29</td>
</tr>
</tbody>
</table>

Specimen Defects ’07-’09

<table>
<thead>
<tr>
<th></th>
<th>Year A [’07-’08]</th>
<th>Year B [’08-’09]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancillary Testing</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Nonrepresentativeness</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Other defects</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>6</td>
</tr>
</tbody>
</table>

Interpretative Defects: Diagnosis Involved ’07-’09

<table>
<thead>
<tr>
<th></th>
<th>Year A</th>
<th>Year B</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Skin</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Cervix</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Prostate</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Breast</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lung</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*an additional oral pathology diagnostic revision
Detection Mechanism ’07-’09

<table>
<thead>
<tr>
<th>Year</th>
<th>Year A</th>
<th>Year B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician Requested Review</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Tumor Board Review</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Other Post-Sign-out Review</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>6</td>
</tr>
</tbody>
</table>

Observations ’07-’09

- Pre-sign out double review may decrease primary interpretation defects
- Interpretation defects are most frequent in high volume specimen types [GI, skin, cervix]
- Identification defects are relatively resistant to interventions

Need for Audit and Editing ‘09

- 2 months’ audit
- 7846 cases reported
- 181 addenda reviewed
- 2.3 addenda/1000 cases

Addenda [ N=181]

- 78 (43%) added GI diagnoses (mostly H. pylori status)
- 34 (19%) added GI diagnoses (no reason supplied)
- 25 (14%) added reports of molecular testing
- 19 non-GI added diagnoses (no reason supplied)
- 6 others [non-GI] added diagnoses (reason supplied)
- 10 changed diagnoses*

* fitting amendment definition

Observations From Audit

- In a substantial fraction of addenda (29%), no reason for addition was supplied
- Two common causes account for 57% of addenda
  - H. pylori reports (43%)
  - Molecular pathology reports (14%)
- Five and half percent (10/181) of ‘addenda’ were really amendments

There were more of these misclassified diagnostic changes during the audit period than there were reported amendments

Conclusions From Audit

- Independent editor of both Amendments and Addenda
- Maintains system integrity
Intervention:
Amended Reports Dictionary
- In real time
- Throughout practice
- One controlling editor
- Consistent classification
- Capturing information
  for root cause analysis

Impact on Process Improvement
- Observed defects rise, then fall
- Untoward increase in report defects
- Multiple observed causes of mis-ID’s:
  (collection, transport, accessioning,
  grossing, cutting)
- Possible decrease in mis-IPs

Sources of “Our” Interpretation
And Specimen Defects
- Non-reproducible diagnostic distinctions
- Distracting histologic backgrounds
- Contrasting histo- vs. cytologic emphasis
- Central vs. peripheral location
  of critical diagnostic findings
- Differing knowledge of clinical context

“Get It While You Can”
(Janice Joplin – Nicknamed ‘Pearl’)
- Defects that cause amendments divide into:
  - Misinterpretations
  - Misidentifications
  - Specimen defects
  - Report defects
- Excellent taxonomic agreement obtained
  within a practice, good agreement among practices
- Classification integrity requires
  real time monitoring and independent editing *
- Defect fractions assess interventions;
  amendment rates assess success
* Strict adherence to definitions of amendments
  vs. addenda, elimination of other ‘change’ categories

References
   Amended reports: Development an validation of a taxonomy.
   Am J Clin Pathol 2008;130:238-246
2. Raab S, Nakhleh RE, Ruby SG. Patient safety in anatomic pathology:
   Measuring discrepancy frequencies and causes.
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4. Nakhleh RE, Zarbo RJ. Amended reports in surgical pathology and
   implications for diagnostic error detection and avoidance.
   Arch Pathol Lab Med 1998;122:303-309

Thanks!

Discussion Topics
- Monitor both addenda and amendments?
- Amended reports measure quality or safety?
- Amend ‘old cases’ when errors discovered?

Collaborators
Richard J. Zarbo, Ruan Varney,
Stephen Raab, Colleen Vrbin
Take Home Messages:

Defects that cause amendments divide into:
* Misinterpretations * Misidentifications
* Specimen defects * Report defects

Excellent taxonomic agreement can be obtained within a practice, good agreement among practices

Classification integrity requires real time monitoring and independent editing*

Defect fractions assess interventions; amendment rates assess success

* Strict adherence to definitions of amendments vs. addenda, elimination of other ‘change’ categories

Syllabus

Introduction: In discussions of quality and patient safety in anatomic pathology, amended reports often appear as potential material for evaluating surgical pathology processes. This presentation proposes a consistent definition of amended reports and a classification of the types of amendments. It shows how this taxonomy has been used to monitor amended reports over several years. The presentation also offers some conclusions that have emerged from this monitoring.

The monitoring characterizes amendments into four classes, relates their frequencies to process attributes, and links process changes to these frequencies. The monitoring experience also introduces three topics for discussion: how should the distinction between addenda and amendments be maintained? What, realistically, do amendments tell about the quality of surgical pathology processes; in particular, do they say anything about patient
From the experience that this presentation describes, we do think that amended reports are indeed sources of evaluation and improvement. Diagnostic anatomic pathology (surgical pathology and cytopathology), fundamentally, turns tissues and cells into information. This product is recorded in reports, so amendments to these reports reveal loss of information or addition of misinformation, which is damaged product. In every production system, responsible producers should attend to their product’s defects.

**Definitions:** Amendments are changes in information – not just additional information – that are made after report are released, that is, ‘signed out’ or published, not before.

Information theory presents the case for amendments as indices of process defects. They are sources of confusion that revised previous information: in information theory this confusion is “noise”. Noise breeds distrust among people (“receivers”) who wonder how much they should rely on the information (“signal”) that they receive. These “receivers” are presented with the question: should I trust “signal” from this “source”? The answer to this question depends on how often the “source” generates "noise" or transmits through “noise”: this is the “signal to noise ratio”. Beyond the distrust, amendments generate – indeed they are – rework; they otherwise unnecessary “retransmissions of signal”. Finally, in an information system, “noise” patterns may be instructive manifestations of unwanted variation (“interference” in the information theory "system"). In our case, the information system is the diagnostic pathology process.

Reports are also a system-wise domain; all parts of the pathology enterprise, as their raison d’être, produce reports. We hope to show in this presentation, that a valid taxonomy can classify amendments consistently. Such consistent classification, in turn, can be used to generate two kinds of quantified monitoring indices: defect rates and defect fractions. We have tried to use the defect rates to monitor our product and its “signal to noise ratio”. We have tried to use the defect fractions to monitor interventions to decrease defects, that is, interventions that decrease “interference”.

The initial hurdle to get over in the study of amended reports is the ambiguity of nonstandard terms for altered reports: addendum, addition, amendment, correction, and revision – presented here in alphabetical order – were all descriptive designation used in our practice without clear distinctions separating one from another.

We replaced this vague situation with a two-state terminology. Post- release changes sort into one of two alternative bins: Either amendments – all changes except those that only add information, or addenda – only changes that just add information; addenda may in no way
change information. To avoid confusions about the confusion that post-release changes cause - all other terms must disappear.

**Taxonomy Development:** We developed and validated our classification for amended reports in the following way. First, we examined 141 changed reports, collected over a year. Next, we sorted the changed reports into 4 categories: misinterpretations, misidentifications (mis-IDs), specimen defects, and report defects. We then applied these categories to a new set of a different series of 131 changed reports. We did this with two objectives: classify each defect into one-and-only-one category and achieve agreement among 4 independent observers as to the class in which each amendment belonged. To achieve these two objectives we revised the study definitions. With the revised categories in mind, the four independent observers classified another new set of amendments, this time a series of 430 reports not previously classified. To the observers’ classifications in this validation round we applied the kappa statistic for measuring agreement.

At the time we were doing this, our laboratory was participating in a multi-institutional study of unwanted variation in pathology and cytology organized by Doctors Stephen Raab and Dana Grzybicki. This connection, and the help of the study’s capable staff, permitted us to circulate another set of new cases: fifteen from our practice and fifteen from the pathology practice at University of Pittsburgh Medical Center Shadyside. Practitioners from seven practices evaluated these 30 cases – three of the practices were in the Northeast, one in the Southeast, and three in the Midwest. Again we used the kappa statistic for measuring agreement.

In the validation set (N= 430 cases, all from Henry Ford Hospital), the four initial reviewers demonstrated excellent agreement by kappa measurement: a median kappa of 0.8780 (range: 0.8416 – 0.9144) in this prospective test of their classifying consistency. In the circulation set (N = 30 cases – 15 from Ford, 15 from Shadyside) seven reviewers (including one of the original four) showed very good kappa agreement: a median of 0.6235 (range: 0.3108 – 0.8975) across the different practices.

The validation of taxonomic agreement permits us to use of a pair of quality measures that can follow the ebb and flow of amendments over time: *amendment rates* – annual number of amendments per total number of reported cases – and *amendment fractions* – the percentages of amendments that fall into misinterpretation, misidentification, specimen defect, and – if no other applies – report defect categories. The interactions of these fractions – whether they vary together or not – can be assessed statistically by the Pierson correlation test.

While they do not track product quality as the sources of "interference" (the frequency and distribution of report defects), two other measures are valuable as well. These two measures are valuable as “stratifying variables” – findings that help in the investigation of amendments’
root causes. The measures are “defect discoverers” and “mechanisms of defect discovery”. There are four sorts of defect discoverers: pathologist, clinician, other staff, and unknown, as well as four mechanisms of discovery: clinician call, conference review, pathology review, and other.

**Taxonomic Classes**: Before presenting what the monitoring of amended reports found, we should summarize the major characteristics of the four categories of misinterpretation, misidentification, specimen defect, and report defect.

**Misinterpretations** come in three subtypes. False-positives or “over-calls” add misinformation. False-negatives or “under-calls” miss or lose information. Sometimes diagnoses are rearranged without “over-call” or “under-call”, that is, on the same plane of importance or implication. Changing the name of, for example, a soft tissue sarcoma from that of one entity to that of another when the two names indicate entities of the same degree of malignancy or aggressive behavior would be an example of ‘misclassified’ but neither false-positive nor false-negative interpretation. These three types of misinterpretation, it turns out, appear on two different ‘levels’ of diagnosis. The primary level is that on which changes appear between positive and negative, benign and malignant. The secondary level is home to modifiers of prognosis like changes in grade (histologic appearance), stage (extend of involvement), margin involvement (or lack of such involvement), and the number and extent of involvement of lymph nodes in sections examined.

**Misidentifications** can also happen at different levels: patients can be confused, as can tissues (e.g. stomach vs. colon biopsies), and the laterality of specimens from paired organs (e.g. right vs. left breast) as well as anatomic location within an organ (e.g. skin of shoulder vs. skin of thigh).

**Specimen defects** come in five kinds. Specimens can be completely lost; they can be too small; their descriptions may lack critical measurements; they may not have been adequately sampled; or critical ancillary studies have not been done or the wrong studies were selected.

**Report defects**: If defects that cause amendments do not fall into one (and only one) of the three categories just described, then the sub-type of these report defects is one of three kinds: (i) missing, erroneous, non-diagnostic information; examples of non-diagnostic changes that stimulate amendments are missing or wrong practitioner, procedure, date, or code (physician, diagnostic, or test codes); (ii) dictation or transcriptions that are typographical errors in the strict sense, (iii) failures or aberrations of electronic (computer) formats or electronic transmissions. Please note that changes in diagnosis – those “above the line” – are, by definition, excluded from this default category.
**Monitoring Experience - Development:** With these classifications in mind, we can follow the behavior of amendments over time.

During the taxonomy’s development, retrospective rates (years 1 and 2) proved to be lower (2.6 – 2.8/1,000) than prospective, “real time” amendment rates (3.4 - 4.8/1,000). We point this out as an important finding: *amended report rates in systems in which interventions are yet to be undertaken rise with real time monitoring.*

Over the period of the classification’s development, among the four defect categories, misinterpretations made up the most consistent fractions of 23% -29% of defects. The Pierson test found misidentifications and report defects to be reciprocally linked: misidentifications fell as report defects rose. Perhaps, this connection is due – like the rise in “real time” amendment rates - to the increased attention we paid to amendments.

Regarding the reciprocal relationships, increased attention may have led to both more pre-publication detection of misidentifications, lowering that rate, and more post-publication awareness of report defects, leading to their amendment. Specimen defects followed a “ping pong” pattern that has continued over all the years that we have followed them: lower one year then higher the next year, then lower again; this lack of a consistent downward trend has been frustrating, but specimen defects make up the smallest of the four fractions, they “bounced” between 4% and 10% during the initial phase of our study.

Before we look at the impact of various interventions on these indices, we should summarize the ‘baseline state’ from which we set out on our ‘quality journey’. At that point, the amendment rate (225/46,468) was 4.8/1000 with 24% (53) misinterpretations, 19% (44) misidentifications, and 9% (20 specimen defects and almost half, 48% (108) report defects.

Regarding the stratifying variables of defect discoverer, at baseline pathologists discovered almost three-quarters (74%) of misinterpretations and 44% of report defects (more than any other discoverer category). Clinicians discovered two-thirds (66%) of misidentifications.

Regarding the stratifying variable of defect discovery mechanism, most interpretations (83%) were discovered preparing for, at, or after clinical pathological conferences – a point to which we will return. Most (two-thirds) of misidentifications came to light during or following calls from clinicians.

Also before launching into our account of amended report monitoring with the validated taxonomy, we should stress four points that we learned from the classification development project. First, excellent agreement within institutions and good agreement among different institutions can be attained, but the classification must be consistently applied to obtain comparable results among sites and over time.

Second, achieving consistent application of the classification requires an independent editor using objective criteria to prevent, for example, self-serving ‘addenda’ in which ‘benign
prostate tissue’ becomes ‘prostatic adenocarcinoma’ without the change being recognized as a misinterpretation. Besides being ignored, classification criteria can be misapplied: when samples have been confused, a report amended from ‘intradermal nevus’ to ‘eccrine poroma’ is not due to a report defect but due to misidentification. Failure to dig down to the amendment’s root cause can lead to the change from ‘mild dysplasia CIN1’ to ‘focal severe dysplasia CIN3’ being misattributed to defective interpretation when the change proves due, in actuality, to a specimen issue, inadequate sampling: the higher grade lesion appeared on deeper levels.

Third, there is a big difference between the lower level of amendments that appears with passive monitoring (not quite 3/1000) and the higher rate that appears with active monitoring (almost 5/1,000).

Finally, during the taxonomy’s development phase, conference reviews appeared as a very important mechanism for amendment discovery in the baseline state: in our experience getting ready for conferences, presenting at conferences (like tumor boards), and following up on issues that conference discussions raised detected raised detected ten to twenty percent of all defects, half of misinterpretations during passive monitoring period and four-out-of-five misinterpretations during active monitoring. Institutions following in our footsteps should keep these four points in mind: consistency can be achieved, that it requires an independent editor using objective criteria, that there is a big difference between passive and active monitoring in terms of detection rates, and that conference review is the most important amendment discovery mechanism in the baseline state.

**Monitoring Experience – Application:** The four defect categories apply to a sequence of events that make up the surgical pathology process. First in the sequence is patient and specimen identification, monitored by the defect category of misidentification. Second in the sequence is specimen handling, monitored by specimen defects. Third is diagnostic interpretation, monitored by the category of misinterpretation. Last in the sequence is result reporting, monitored by report defects.

To this sequence we applied the measures of total amendments per year and the rates of amendments per thousand cases to assess trends in amendment frequency, and the fractions of the four defect types divided by the amendment totals to assess the distribution of amendment types.

The sequence of events in the surgical pathology process is always a work in progress, always undergoing modification. The years in which we applied the amended report taxonomy to the surgical pathology process at Ford, we saw three important modifications that affected the sequence. Amendment editing as a real time application of the classification began in 2005; the LEAN principles of the Henry Ford Production System
(HFPS) were introduced, including interventions into the first two steps in the sequence, patient and specimen identification and specimen processing in 2006; the HFPS had informed the whole sequence by 2007. The process changes were associated with interesting changes in the measure of amendment rates. (See the table tallying these changes from the Power Point presentation accompanying this syllabus: Monitoring Results I: Defect Totals.)

The introduction of amendment process editing was associated with a doubling of observed amendments per thousand cases between the baseline year of 2004 and 2005, from 4.8/1,000 to 10.1/1,000. During the first year of the Production System’s changes specifying and standardizing the steps in the process to reduce batching and cut cycle terms, defects fell 20%, from 10.1/1,000 to 7.8/1,000. As the HFPS permeated the whole process, producing a redesign of specimen and information flow, focus on decreasing process defects and reducing re-work, the amendment rate fell another 15%, from 7.8/1,000 to 6.3/1,000 between 2006 and 2007.

Over the same period, changes in the fractions of defects in different categories were also of interest. These changes are summarized in a Table entitled “Results II: Monitoring Defect Fractions” in the accompanying Power Point presentation.

During the four year period, the misinterpretation fraction fell 70%, from almost a quarter of all defects (23.5%) in 2004 to 7% in 2007. This fall was steeper after the HFPS’s full implementation in 2007: the decline in the fraction between 2006 and 2007 was from 16% to 7%, so the fractional contribution of misinterpretation more than halved.

Misidentification fractions fell 4% between 2004 and 2005, and 3% between 2005 and 2006, but then leveled off in 2006 and 2007 at 12% of all defects. Specimen defects were the fewest in the first three years: they declined steeply, from 9% to 2% between 2004 and 2005, then rebounded to 4.3% in 2006, and rose to its highest fraction (11%) in 2007, the year when the misinterpretation fraction became the smallest fraction of defects. As the other fractions fell, report defects increased from 48% to 64% to 68% to 70% at the application period’s end.

In these changes we see that the HFPS’s interventions had more impact on identification and interpretation defects and less impact on specimen defects. The report defection fraction, one should remember, is the “default category” that increases as the other fractions decrease.

**Monitoring Experience: Second Phase:** As we continued monitoring into 2008, we focused on the three major initiatives of the HFPS in the surgical pathology process. These entailed, first ‘goal-directed’ education of the clinical staff (nurses, office staff, and physicians) to change their specimen labeling process to eliminate misidentifications. In the process phase of specimen handling we redesigned and change our own specimen accession
(identifying, describing, sampling, cassetting, and fixing) process. In the third phase of
diagnostic interpretation, the Ford surgical pathologists adopted a practice of pre-sign-out
double reading of breast and prostate specimens were introduced. This double review
involved about 800 of about 47,500 cases a year, so 2% of all cases.

Over the period that we monitored these three interventions, total amendments fell steadily
from 374 to 261 a year, that is, from an amendment rate of 7.8 to 5.5/1,000. Focused
double reviews of a small fraction of cases were associated with an 88% decrease in the
amendment fraction: from 16% in 2006, through 7% in 2007, to 2% in 2008. We hasten to
add here that this is a real world association not the conclusion of a well-controlled
experiment. Undetected confounding factors may have also contributed to this fall.

The “front end” effort to improve patient and specimen identification has no initial impact
on the misidentification factor – which was 12% in both 2006 and 2007 – but it was
associated - perhaps rewarded with a striking decrease, from 12% to 5%, between 2007 and
2008. Accession redesign was associated with an initial rise in specimen defects, from 4%
to 11% between 2006 and 2007, then a return to 3% in 2008 (still not as low as the 2%
recorded in 2005). This set of observations, illustrates how the amendment totals and rates
can be used to check the overall trend associated with improvement initiatives, while defect
fractions can be used to examine the specific impact of particular interventions.

**Connection of Monitoring to Process:** If one looks at the relation between amendment
rates and fractions between 2004 and 2008 and the simultaneous changes in our surgical
pathology processes, one finds four “take home messages” from on-going amended report
monitoring.

First, pathologists “finalling” reports themselves (rather than with the help of
transcriptionists) greatly increased report defects (missing or erroneous non-diagnostic
information: practitioner, procedure, date, various codes, etc.) at the beginning of the
monitoring period. By the end of the period--we have recounted-- defects in this category
accounted for 90% of report revisions. Second, editing – introducing systematic
amendment classification –increases defect detection. Third, the Henry Ford Production
System LEAN initiatives did indeed reduce defects, but the impact was greater on some
defect types (misidentification and misinterpretation) than others (specimen defects).
Fourth, this impact grew with ongoing, widening integration of the LEAN principles into
daily practice. Relevant to the last point, the impact of efforts to standardize clinicians’
specimen collection and labeling practices on misidentifications took two years before a
decline appeared in the fraction of this sort of defect.
Finally, some challenges are difficult. The specimen processing re-design led initially to an increase in recorded defects then a decrease to the previous level but – at this point in the monitoring – without achieving a major quality breakthrough.

**Monitoring Experience - Continued Application:** Over a more recent two year space (2007-2009), we have focused attention in greater detail on the 10% of amendments due to interpretation, identification, and specimen defects.

First, we compared amendments between mid 2007 and mid 2008 and mid 2008 and mid 2009. Amendment rates continued to fall, over this time span from 7/1000 to 5/1000. This decline was reflected in two of the categories. For interpretation defects the decline was mostly due to a decrease in amendments of primary diagnoses. Among identification defects, patient misidentification was the most frequent defect in both years but the most prominent finding was rise, almost threefold, in laterality confusions. The decrease in specimen defects which finally appear to be trending down - can be traced to elimination of defects associated with ancillary testing.

In both years, GI and skin specimens remained the most frequent sources of interpretation defect with cervix and breast specimens also appearing in both years, but prostate, kidney, lung, and thyroid specimens coming and going from the list.

In the second year both clinical and conference review were less frequent discovery mechanisms.

As we continue to monitor amendments, four observations seem to be holding up. Pre-sign out double review of breast and prostate specimens appears worthwhile. Identification defects, at their new lower level, have again become relatively impervious to continuous improvement by our current intervention. Interpretation defects are more frequent in high volume (GI, skin, and cervix) specimen types.

**Importance of the Edit Function:** In early 2009 we again had to make the case for an independent editor. During a 60 day period – over which 7,846 cases were reported – 181 addenda were added (2.3 addenda/1000 cases). The biggest fraction of these additions (43%) was added GI diagnoses for which a reason was supplied (mostly statements of *H. pylori* immunostain results). Another relatively large group (19%) was also made up of GI diagnoses, but no reason for the additions was obvious in these cases. Fourteen percent of addenda were added molecular pathology test reports, so – *H. pylori* immunotesting and molecular testing account for over half (57%) of addenda. It is troubling, however, that no reason for an addendum was supplied in not only the 34 GI cases mentioned above but also in another 19 cases, so a large fraction (29%) of addenda was in instances in which the reason for amending could not be determined in retrospect. Even more troubling was the turning up of 10 cases in
which amendments had masqueraded as addenda: 5.5% of addenda should have been classed as amendments. In fact, there were more of these misclassified diagnostic changes during the period of our addenda audit than there were reported amendments. We took the finding of this audit to indicate that the independent editors need to review both amendments and addenda to maintain system integrity.

Conclusion: We have found value in the application of an amended reports dictionary in real time, throughout the practice, by one controlling editor, using a consistent classification to capture information for root cause analysis. Studying amended reports in this way during a period of LEAN process improvement saw observed defects first rise, then fall, recorded an untoward increase in report defects, and found multiple observed causes of misidentification at collection, transport, accessioning, grossing and cutting steps in the process. It also witnessed a decrease in misinterpretations that may indeed be real and substantial.

Misinterpretations: An Interesting But Difficult Problem: Interpretation defects may, however, be relatively difficult to approach systematically. There are five themes that emerge from their study as they surface in amendments that suggest how this might be true. The first is that some of the diagnostic distinctions that pathologists use, especially to describe the lowest grade borderlands of neoplasia, are not reproducible among observers. The second theme is that distracting histologic backgrounds increase the risk of misinterpretation. The third theme is that observers’ different emphasis on histological versus cytological appearances can lead to differences in diagnostic interpretations. Fourth, if an observer discovers a finding in a peripheral zone of a slide, he or she may neglect another finding in a central zone, or vice versa. Finally, in some situations, only differing knowledge of clinical contexts seems to drive diagnostic discrepancies.

Pathology Pearls: The string of four pearls that we can offer from our seven years study of amended reports are: defects which cause amendments divide into misinterpretations, misidentifications, specimen defects, and report defects; excellent taxonomic agreement in the application of this classification can be obtained within a practice and good agreement among several practices; consistent classification requires real time monitoring of both amendments and addenda by an independent editor. Finally, defect fractions assess interventions and defect rates assess success.

On the last slide in the Power Point presentation appears -- along with thanks for interest in the topic-- three questions for its audience to consider. Are you persuaded by our argument that both addenda and amendments require monitoring? Do amended report rates and distributions measure only product quality or do they also index safety? Should cases published years before be amended in the context of much later diagnostic developments?
The last slide also acknowledges long term collaborators in the study of amended reports: Richard Zarbo is the Chairman of Pathology and Laboratory Medicine at Ford and the enlivening spirit of our HFPS approach to improvement. Ruan Varney has managed the amended report dictionary from the beginning. Stephen Raab joined in our initial development of the taxonomy and – with his research assistant from Pittsburgh days, Colleen Vrbin - carried out the inter-practice comparison.
Critical Values and Persistent Challenges in Communicating Pathology Results

Jeffrey L. Myers, MD
A. James French Professor & Director, Anatomic Pathology
University of Michigan, Ann Arbor, MI
myerjeff@umich.edu

Objectives
At the end of this presentation attendees will understand
• expectations & challenges in effectively communicating critical values in AP

2010 National Patient Safety Goals (NPSGs) of The Joint Commission:
"The purpose of The Joint Commission’s National Patient Safety Goals (NPSGs) is to promote specific improvements in patient safety.”
2010 National Patient Safety Goals (NPSGs)

The Joint Commission

Goal 1: Improve the accuracy of patient identification

Goal 2: Improve the effectiveness of communication

Goals 3-6: Reduce the risk of health care-associated infections

Goal 7: Reduce the risk of health care-associated infections

Goals 8-16: Reduce the risk of health care-associated infections

†http://www.jointcommission.org/

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Improving Effectiveness of Communication

Reporting Critical Results – Performance Elements

Develop written procedures

– definition

critical diagnoses

abnormalities that can be potentially life threatening and require rapid corrective action for improvement of patient outcome

†ADASP 2006

†http://www.jointcommission.org/

Critical Diagnoses in Anatomic Pathology

Examples (ADASP 2006)

Findings with immediate clinical consequences

– crescents in > 50% of glomeruli
– leukocytic vasculitis
– uterine contents without villi or trophoblast
– fat in endometrial curettings or colonic endoscopic polypectomies, mesothelial cells in heart biopsies
– transplant rejection
– malignancy in superior vena cava syndrome, paralysis

Unexpected or discrepant findings

– disagreement between frozen section and final dx
– disagreement between immediate and final FNA dx
– disagreement with outside interpretation

Infections

– bacteria/fungi in CSF, heart valves, or bone marrow
– Pneumocystis, fungi, virocytes in pulmonary secretions
– AFB
– any invasive organism in immunocompromised patients

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Improving Effectiveness of Communication

**Develop written procedures**
- **CAP (ANP.12175)**
  - **significant or unexpected** surgical pathology findings

---

**Customer Satisfaction in AP**

**Median for Excellent/Good Ratings for Each Service Category**

<table>
<thead>
<tr>
<th>Service Category</th>
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<tbody>
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---

**Designing for Safety in Health Care**

AHRQ Survey on Patient Safety Culture: 2006 Report

---

**Medical Errors – “Very Important” Causes**

<table>
<thead>
<tr>
<th>Cause</th>
<th>MDs</th>
<th>Public</th>
</tr>
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<tbody>
<tr>
<td>insufficient time spent with patients</td>
<td>37%</td>
<td>72%</td>
</tr>
<tr>
<td>overwork, stress, fatigue</td>
<td>50%</td>
<td>70%</td>
</tr>
<tr>
<td>failure to work together or communicate as team</td>
<td>39%</td>
<td>67%</td>
</tr>
<tr>
<td>understaffing of nurses</td>
<td>53%</td>
<td>65%</td>
</tr>
<tr>
<td>complexity of care</td>
<td>38%</td>
<td>62%</td>
</tr>
</tbody>
</table>

---

**2010 National Patient Safety Goals (NPSGs)**
The Joint Commission

**Goal 2 – Improve the effectiveness of communication among caregivers.**
- Report critical results of tests and diagnostic procedures on a timely basis (NPSG.02.03.01)
- Quickly get important test results to the right staff person.

This is an easy-to-read document. It has been created for the public.

---

**Designing for Safety in Healthcare**
Report of the Institute of Medicine (IOM) Committee on Quality of Health Care in America
November, 1999

- Provide leadership
- Respect human limits in process design
- Promote effective team functioning
- Anticipate the unexpected
- Create a learning environment
Anticipate the unexpected

What if no one sees my report today?

... tomorrow?

... ever?

What if no one sees my report today?

Improving Effectiveness of Communication
Reporting Critical Results – Performance Elements

Develop written procedures
– definition
– by whom and to whom

... using what standard process and which tools?

http://www.jointcommission.org/

Handoffs & Transitions

screening colonoscopy ordered

bx of susp polyp ("R/O cancer")

primary care provider (PCP)
Handoffs & Transitions

life threatening?

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GI doc

bx = adca

Handoffs & Transitions

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Improving Effectiveness of Communication
Reporting Critical Results – Performance Elements

Develop written procedures
- definition
- by whom and to whom
- criteria for *timeliness*

*http://www.jointcommission.org/

Improving Effectiveness of Communication
Reporting Critical Results – Rationale

The *objective* is to provide the responsible caregiver these results within an established time frame so that the patient can be promptly treated.

*http://www.jointcommission.org/

Customer Satisfaction in AP

Median for Excellent/Good Ratings for Each Service Category

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Handoffs & Transitions

**Vasculitis**
14% 31% 55%

**Neoplasms causing paralysis**
20% 20% 60%

**New diagnosis of malignancy, with clinical suspicion**
62% 28% 10%

Designing for Safety in Health Care

Communicating (“Critical”) Diagnoses

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Routine report</th>
<th>Phone call within 24 hrs</th>
<th>Phone call ASAP</th>
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What if no one sees my report today?

Anticipate the unexpected
**Improving Effectiveness of Communication**

**Reporting Critical Results – Performance Elements**

- Develop written procedures
  - definition
  - by whom and to whom
  - criteria for timeliness
- Implement the procedures

---

**Significant & Unexpected/Critical Diagnoses**

**in Surgical Pathology**

- Do you have a written policy regarding anatomic pathology critical values or diagnoses? - **YES**
- n = 817
  - 75% General guideline without specific conditions
  - 25% General guideline with a few (= 5) specific examples
  - 33% General guideline with many (> 5) specific examples
  - 19% Strict policy with specifically defined list of diagnoses

---

**Improving Effectiveness of Communication**

**Reporting Critical Results – Performance Elements**

- Develop written procedures
  - definition
  - by whom and to whom
  - criteria for timeliness
- Implement the procedures
- Evaluate the timeliness of reporting

---

**Monitoring Critical Diagnoses**

**at The University of Michigan**

natural language parser

- key phrases ≠ malignancy
- procedure ≠ excision/resection
- key phrase ≠ notification

signing faculty

- clinical notes
- appointments

Director of Surgical Pathology

- policy filter
- EMR reconciliation

---

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Monitoring Critical Diagnoses at The University of Michigan

10,433 events in 3 years
13.3 ± 5.9 per day (range 0 – 39)
29 (0.3%) actionable

Case 1
colon bx = invasive adca in patient undergoing average risk screening with no acknowledgement in EMR and no return appointment
ACTION: gastroenterologist confirmed plan to communicate to PCP

Case 2
unexpected diagnosis of lymphoma in sentinel LN done for melanoma
ACTION: confirmed with signing pathologist that provider had been contacted (not documented)

Critical Values and Persistent Challenges in Communicating Pathology Results

Key Points

• effective communication of significant results means having a plan to ensure information gets to the right person at the right time
• start by developing a policy in collaboration with providers
• implement – and document performance as measured against – your plan
Cytopathology-Histology Correlations

Andrew Renshaw, MD
Baptist Hospital of Miami
Miami, FL

Objectives

- What to correlate
- When to correlate
- How to correlate
- Why correlate
- Expectations/Goals

What to correlate

- All in house cases
- Selected out of house cases
  - Hospital policy for review of slides
  - Physician request
  - Select cases of interest
  - Bill - price of using low cost provider
- Other tests (flow, cytogenetics, Her2Neu)
- ? Electronic medical record?

When to correlate

- Time of sign out
  - Standard of care
  - No one is interested in your explanations 2 months later
  - Does bias result -
    - Know f/u
    - Cover your own tracks - 2nd reviewer?
    - worth it

How to correlate

- Identify case
- Identify cause
Identify case

- Look up history of every case
  - Standard of care
  - Clinician will not tell you

Identify cause

- Sampling, regression, progression, interpretation
- Lack of agreement for interpretation
  - No blame box
  - Outside consultant
  - If doc won’t admit error probably have a problem

Why correlate

- Identify future problems for the patient
- Identify problems in the lab
- Monitoring improves performance: real feedback (APLM 132; 13)

Identify future problems for the patient

- Usually do not need to admit liability in your report - not a future problem, sometimes need to call your lawyer first
- Often better with a phone call
- Do need to direct clinician for more sampling
  - HSIL on Pap is real
  - No biopsy site in breast excision

Identify problems in the lab

- Single case versus trends
- Need to summarize results q 6-12 months
- Do need to track by pathologist - most important cause of error in diagnosis

Expectations/goals

- Pap smears:
  - HSIL bx, neg Pap (look back)
    - Required but no agreed on expectations
    - Some interpretation errors (5-30%?)
  - HSIL Pap, neg bx
    - <5% interpretation errors ASC-H
  - HPV rate for ASC and NILM?
Expectations/goals

- **Thyroid FNA** -
  - FNR <1%
  - FPR 0%
  - No standard for atypicals, follicular lesions

- **Cores**
  - >90% sampling
  - ?harder to interpret pap ca on core?

Expectations/goals

- **Breast core** -
  - FNR all sampling and documented in the core
  - FPR 0%
  - ADH not DCIS, send out afterward
  - High grade DCIS send out first
  - Small inv ca - sus and send out afterward

Expectations/goals

- **Fluids**
  - FNR - interpretation <5%
    - Known patterns
    - Lobular ca, small cell ca, rare cells
    - Should be using IPOX routinely
  - FPR
    - 0%
    - Rare tumor cells - sus and repeat

Expectations/goals

- **Lung FNA**
  - Subtyping
    - Poorly dif carcinoma with features of both
      - recommend repeat (1-5% of cases)

Summary/Pearls

- DO C-H correlation at time of sign out
- Summarize q6-12 months by doc
- Interpretation errors should be rare
  - If doc won’t admit error have a problem
  - Most interpretations errors can be avoided if you know where the pitfalls are:
    - PD lung ca
    - Rare atypical cells in fluid -sus
    - Breast core: ADW not DCIS
    - Thyroid: rare atypical cells - not negative
    - Paps: rare cells -ASC-H

Thank you for participating!
Cytologic correlation (and it’s close cousins cytologic – cytologic correlation and histologic- histologic correlation) is a routine part of quality assurance in any pathology laboratory. This review focuses on what to correlate, when to correlate, how to correlate, why correlate, and what a laboratory director’s expectations and goals might be. The data is derived from the literature and my personal experience.

I believe all in house cases should be correlated. I only correlate out of house cases when there is a hospital policy for review of slides, a physician requests it, or I have a particular interest in the case. My opinion is that reviewing outside cases is part of the price the insurer bears for insisting that their pathology goes to a low price laboratory rather than to me, so I make sure I bill for it. It is also important to correlate diagnoses with the results of other tests (flow, cytogenetics, Her2Neu), and this is a new CAP Checklist question in anatomic pathology (3). In only a few months this has already lead to changes in diagnosis twice in our laboratory. Since it is easy to overlook, a more formal process may need to be put in place for this to occur.

I strongly believe that all cases should be correlated at the time of sign out. I personally look up the history on every single case, since I know many clinicians won’t bother to tell me what they already know. While there is no accepted standard, I believe this is standard of care. No one is interested in your explanations 2 months later, and preventable patient harm can occur in that interval. This does bias the results – you know the follow-up, and one generally tries to make things correlate. Also there may be a temptation for an individual pathologist to cover up his own errors. Nevertheless the chance to prevent harm makes it worth it.

It is important to identify the cause of any discrepancy. The most common causes are sampling, regression, progression, and interpretation. The literature suggests that there may be a lack of agreement on interpretation as a cause for discrepancy (8, 9). One solution in the literature is to use a No blame box (9). Our approach has been to send the case to an outside consultant. It is my experience that if a pathologist routinely has trouble acknowledging an interpretation error, there are larger problems with his or her performance than that individual case.

When correlating I attempt to identify future problems for the patient and problems in the lab. It has also been shown that monitoring cytologic histologic correlation improves performance (7). This is another example, like pre-screening rather than re-screening Pap
smears (1), where more formalized and accurate feedback can lead to improvements that less formal and accurate feedback can not achieve.

While one always has to make the correct diagnosis in the report, one usually does not have to admit liability in the report. When faced with this, one may need to contact one’s lawyer first and then call the physician before signing the report. More often, one needs to direct the clinician to obtain more tissue sampling, for example when the HSIL on the Pap is real or there is no biopsy site in a breast excision. Phone calls are often helpful in this setting as well.

To identify problems in the lab, trends are often more helpful than individual cases, so there is a need to summarize the results every 6-12 months. It is important to track errors by individual pathologists since this has been shown to be the most important cause of error in diagnosis in most settings (10).

Based on my personal experience and the literature, the following results might be expected:

- Pap smears:
  - HSIL bx, neg Pap (look back)
    - Required but no agreed on expectations
    - Some interpretation errors (5-30%?)
  - HSIL Pap, neg bx
    - <5% interpretation errors ASC-H

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Cytopathology-Histology Correlations
Andrew A. Renshaw, MD

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**Lung FNA**
- Subtyping
  - Poorly dif carcinoma with features of both recommend repeat (1-5% of cases)

In summary, cytologic histologic correlation is best done at the time of sign out so the clinician can be directed to adequately take care of the patient in a timely manner. Nevertheless, the results need to be summarized every 6-12 months to look for trends among individual pathologists. Interpretation errors should be rare. Most interpretations errors can be avoided if you are familiar with the pitfalls and know the ways around them.

References


4. David O, Cabay RJ, Pasha S, et al. The role of deeper levels and ancillary studies (p16(Ink4a) and ProExC) in reducing the discordance rate of Papanicolaou findings of high-grade squamous intraepithelial lesion and follow-up cervical biopsies. *Cancer Cytopathol* 2009;117:157-166.


