Quality Control and Assurance in Anatomic Pathology: The Moffitt Experience

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QUALITY CONTROL AND QUALITY ASSURANCE

• Quality control is a system for verifying and maintaining a desired level of quality in a test or process. Quality control practices span the entire testing process, from collection to the time the clinician receives the report.

• Quality assurance is defined by CAP as systematic monitoring of QC results and quality practice parameters to assure that all systems are functioning appropriately. QA is the coordinated effort to bring together the various activities in the lab that are designed to detect, control and prevent the occurrence of errors.
Changing Times

• Change to pay for Quality
• Patient empowerment
• Reduced tolerance of error
When things go wrong in pathology
Test cycles

- **Pre-Analytic**
  - Specimen collection and fixation, specimen delivery, specimen identification, adequacy of clinical history, accessioning

- **Analytic**
  - Frozen sections, gross processing, histology processing, final diagnosis

- **Post-Analytic**
  - Transcription, verification, report delivery, incomplete report, correlation of diagnostic finding is what ancillary studies
Error rates in each cycle

• Pre-analytical
  – Wrong-identification: 27-28%
    • Most often discovered by clinicians
  – Defective specimens: 4-10%

• Analytic
  – Misinterpretations: 23-29%
    • Most often discovered by pathologists

• Post analytic
  – Defective report: 29-44%
    • Discovered by clinicians and pathologists

*Am J Clin Pathol* 2008;130:238-246
Pre-Analytical Errors

• Patient misidentification
• Specimen misidentification
• Collection and fixation of specimen
• Clinical history
• Transport
• Accessioning

Am J Clin Pathol 2008;130:238-246
Analytic Phase
Reducing Errors and Improving Interpretative Diagnostic Accuracy

- Depends on the pathologist’s ability to interpret morphological findings
- The pathologist’s knowledge, training and experience or expertise
- Utilization of standardized terminology and diagnostic criteria
- Clinical correlation
- Utilization of confirmatory diagnostic ancillary studies
- Additional examination of cases: secondary review process
Post-Analytic Phase

- Proofreading
- Report completeness
- Report Delivery to clinician
- Communication of critical/urgent results
- Communication of additional ancillary findings
Quality Control Processes in AP

- Focused professional practice evaluation for first 3-6 months of new hires; ongoing professional practice evaluation
- Second expert review all new Moffitt patient’s pathology
- Tumor board presentations
- Policies regarding consultations – managing major errors
- Synoptic use mandated
- Daily Microscope rounds for consensus
- Formal intradepartmental consultations
- Monthly QA meeting (mandatory)
- Identification and monitoring of key pathology indicators (Ongoing)
- Monthly Pathology Mortality and Morbidity Rounds (2014)
- Creation of Pathology safety Committee (2014)
- Critical Incident Review
- Use of external Proficiency testing and reviews in cytology
- Use of customer (clinical faculty) satisfaction surveys
Components of Moffitt QC of Analytical Phase

- QC of grossing
- Prospective peer review of new diagnoses of cancer
- Retrospective review for tumor boards
- External peer review
- Monitoring rates of atypia in cytology
- FS to final discrepancy
- Cytology to histology correlations
GROSSING QUALITY IMPROVEMENT AND CORRELATION SHEET

DATE:     /     CASE:  
PATHOLOGIST:  

PATHOLOGIST ASSISTANT or RESIDENT:  1  2  3  4  5  Resident/Fellow (   )

INTRAOPERATIVE CONSULTATION (IC)  Yes  No

GROSSING:  □ Excellent  □ Satisfactory  □ Less than optimal  □ Unsatisfactory

Patient impact:  Yes  No

UNSATISFACTORY REASON:

□ Additional sections needed for diagnosis (example, margins, skin, etc.)
□ Missed tumor
□ Missed biopsy site
□ Missed Lymph nodes
□ Inadequate LN sampling
□ Missed positive LN
□ Tumor size
□ Tumor location
□ other:  

Explain:

SOLUTION:

CASE DISCUSSED WITH PA:  Yes  No  By:  Date
Criteria for Grossing QA

• Unsatisfactory

• Major errors in description or cutting, such as:
  • A) Missed tumor
  • B) Inadequate or incorrect sampling of margins
  • C) Lost tissue
  • D) Missing major elements of template.
  • E) Tumor size that affects staging
  • F) Margins cannot be determined
  • G) Ink contamination or lost tissue
  • H) Tissue orientation is lost
  • I) Section are taken in the wrong direction
  • J) Specimen cannot be reconstructed for a second look
  • K) Specimen has been compromised beyond repair during grossing
  • L) Inadequate number of lymph nodes for which additional lymph nodes are recovered on the subsequent re-examination.
Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology

Guideline From the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology

Raouf E. Nakhleh, MD; Vania Nose, MD, Ph.D; Carol Colasacco, MLIS, SCT(ASCP); Lisa A. Fatheree, SCT(ASCP); Tamara J. Lillemoe, MD; Douglas C. McCrory, MD, MHS; Frederick A. Meier, MD; Christopher N. Otis, MD; Scott R. Owens, MD; Stephen S. Raab, MD; Roderick R. Turner, MD; Christina B. Ventura, MT(ASCP); Andrew A. Renshaw, MD

How well are we doing in diagnostic accuracy?

Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology
Guideline From the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. Arch Pathol Lab Med 2015

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Recommendations

1. Anatomic Pathologists should develop procedures for the review of selected cases to detect disagreements and potential interpretative errors.

2. Anatomic pathologists should perform case reviews in a timely manner to avoid having an impact on patient care.

3. Anatomic pathologists should have documented case review procedures that are relevant to their practice setting.
Recommendations CONT.

4. Anatomic pathologists should continuously monitor and document the results of case reviews.

5. If pathology case reviews show poor agreement within a defined case type, anatomic pathologists should take steps to improve agreement.
What is a major discrepancy?

- (1) differences with demonstrated impact on patient care,
- (2) differences with potential impact on patient care, and
- (3) differences that indicate substantial diagnostic changes (i.e., benign and malignant or positive and negative diagnoses), without regard to actual or potential clinical impact.
Secondary Review
Benefits to Patient Safety

• 1. Second reviews successfully detect and reduce errors.
• 2. Groups that do second reviews have a lower error rate than if they did not perform second reviews.
• 3. Groups that perform second reviews have a measure of quality that may be of use within the group.
• 4. Groups that perform second reviews and fail to detect significant errors (,1 per 1000 cases) may have a problem with the sensitivity of their second reviews.
REVIEW PATHOLOGY

• WE recommended that all cancer patients have second opinion pathology to confirm a malignant diagnosis

• Ideally EXPERT review pathology should be performed before commencing definitive treatment
Consensus Conference

• Daily- timely / quick
• Opportunity for interaction between pathologists
• “calibration” of calls of atypia etc
• Knowledge sharing
• Not always documented
• May not be thorough
Subspecialty Practice

- Essential for high complexity and large academic practices
- Team oriented approach
- Enables academic development
- Enables creation of education programs and fellowships
- May not be as efficient
- Can be hard to justify to hospital administrators
- May only have one expert creating challenges for coverage and quality
Challenges of Internal Review

- Only 1-3 experts in each subspeciality practice
- Challenges of peer reviewing colleagues
- Colleagues may be mentors, former students, or professional rivals
- Can turn into conflicts or “rubber stamping”
- Uncertain of broader quality standard in exotic practice subspecialties
Reducing Errors

• Additive value
  – clinical correlation
  – standardization of diagnostic criteria, and taxonomy
  – Confirmatory ancillary testing

• The pathologist’s knowledge and experience remain the essential factors in interpretive diagnosis.
Multidisciplinary from Inception

Clinical Departments
- Blood & Marrow Transplantation
- Comprehensive Breast Cancer
- Cutaneous Oncology
- Endocrine Tumors
- Gastrointestinal Oncology
- Genitourinary Oncology
- Gynecologic Oncology
- Head & Neck Oncology
- Malignant Hematology
- Neuro-Oncology
- Pain & Palliative Care
- Sarcoma
- Senior Adult Oncology
- Thoracic Oncology

Scientific Programs
- Cancer Biology & Evolution
- Immunology
- Chemical Biology and Molecular Medicine
- Cancer Epidemiology
- Health Outcomes & Behavior
Tumor Boards

- Vital activity at moffitt – weekly for each group so 2 per day
- Enables pathologists to interact with oncologists and others team
- Enables pathologists to learn about impact and value of diagnosis
- Pathologists may get additional information about case (ie history, previous treatment)
- Opportunity for pathologists to have spotlight
- Issues occur when there is disagreement within department over diagnosis
- Problems getting outside materials
- Quality of outside materials can be problematic
Thyroid FNA reporting before Bethesda system

• Interpretation
• A. Consultation, FNA Right Thyroid (2 slides labeled RCM-XX-XXXXXX, dated 10/21/08)
• Hypocellular specimen with micro and macrofollicular patterns and scant cellularity.

• General Category
• Other

• Comment
• Repeat aspirate for definitive diagnosis.
Thyroid Nodule
(Contributing Authors, Version 2015.1 February 5, 2015)

1) Thyroid USS
2) TSH

TSH Low & Not on Suppressive Therapy?

Yes

I\textsuperscript{131} Uptake Thyroid Scan

'Hot' Nodule?

Yes

Treat for Thyrotoxicosis

No

Thyroid USS Show Pure Cyst?

Yes

Pure Cyst

Ultrasound High Risk Surveillance

Thyroid USS and TSH in 6-12 Months

Then 1 Year, 2 Years, and 5 Years

Risk Stratification

Very Low Risk

Low Risk

US Guided FNA Collect Molecular Marker Sample

Ultrasonography Low Risk Surveillance

Thyroid USS and TSH at 1 Year, 3 Years, and 5 Years

Progression

Nodule >1 cm?

Yes

Low Risk

No

US Guided FNA Collect Molecular Marker Sample

FNA Results Available

Progression

Nodule >1.5 cm?

Yes

Very Low Risk

Low Risk

Ultrasonography High Risk Surveillance

Thyroid USS and TSH in 6-12 Months

Then 1 Year, 2 Years, and 5 Years

FNA Results Available

Progression

Nodule >2 cm?

Yes

US Guided FNA Collect Molecular Marker Sample

FNA Results Available

No

Nodule >1 cm?

Yes

Ultrasonography Low Risk Surveillance

Thyroid USS and TSH at 1 Year, 3 Years, and 5 Years

Progression

No

No

No

No

Yes

No

Yes

No

Yes

No

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Thyroid FNA Reporting After Bethesda

Specimen Adequacy
Satisfactory for Evaluation.

Interpretation
Benign thyroid nodule, favor adenomatoid nodule (B II).

General Category
No evidence of malignancy in this specimen.
Paris System: Impact of Standardized Terminology and Criteria

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2009 - 6 cytopaths  
2012 - 9 cytopaths  
2015 - 9-10 cytopaths  
2016 - implement Paris 2/16  

Uninc specimens only
Read Back for Frozen Sections

• Per the TJC hospital manual:
  
• PC.02.01.03 EP 20: “Before taking action on a verbal order or verbal report of a critical test result, staff uses a record and "read back" process to verify the information.”

• (This is a direct patient care standard that requires a minimum of 90% compliance)

• There is no TJC/CMS requirement to read/repeat back results unless they are considered “critical” results per our hospital policy.
Case 1: Gastrectomy

- The surgeon sent one margin, either proximal or distal which was submitted entirely for frozen in 4 parts. The surgeon was called and told all four margins were negative.
- The next margin (opposite of above) was reviewed by the pathologist and called in a bit later. This margin was positive. The surgeon was surprised since he was not expecting another result.
- When reporting results, the name of the specimen needs to be specified.

Case 2: The surgeon came in to review their frozen. They heard a malignant diagnosis and did not apparently, hear/understand all the information the pathologist was relaying. The pathologist had actually reiterated the history of malignancy and then proceeded to tell the surgeon that the specimen was negative but he was cutting deepers.
Intraoperative Consultation

Identify yourself
Confirm the patient
Confirm who is receiving the report
Specify which organ/specimen is being reported
Be as clear as clear as possible
Document exactly what was communicated
  Minimize extraneous language
Listen when the communication is relayed and ask for read back (or verification of result)
  Document the read back for each frozen/set of frozens
Ask if anything further is needed
FS to Final Monitor

• Collect both discrepancy and defer rates
Documentation of Frozen section to Final discordance and Discrepancy

- Frozen sections are identified as discordant with the permanent DO NOT REPRESENT A DISCREPANCY:
  - The frozen is negative but the permanent is positive.
    - Document that the frozen is confirmed and the abnormality is only identified on the permanent.
    - No further action required.
  - The frozen shows carcinoma, high grade dysplasia or neoplasia but the permanent is negative
    - Document that the frozen is confirmed but that the abnormality (carcinoma, dysplasia, neoplasia) is lost on the permanent.
    - No further action required.
Documentation of Frozen section to Final discordance and Discrepancy

• Cases are identified as true discrepancies based on the following criteria:
  – The frozen is called negative but retrospective review of the frozen section is unequivocally positive.
  – The frozen is called positive but is negative on retrospective review.
  – The frozen is called adequate for follow-up studies but is inadequate for follow-up studies on retrospective review.
These require further action as follows:

– Notify the frozen section pathologist of the discrepancy and review with them if they are available. If there is a disagreement, refer to a third pathologist. The Director of Surgical Pathology, or other pathologist may serve as the tie breaker.

– Notify the surgeon immediately.

– The results of the review and the communication of the final results to the surgeon must be documented on the final report. Also add an explanation of the reason for the discrepancy.

• Example: The left lateral margin was reviewed by Drs. X and Y and also at our daily Anatomic Pathology Quality Assurance Conference. The atypia seen on the frozen section is confirmed as reactive by retrospective comparison to the permanent. The final results on the left lateral margin were communicated to Dr. Y by Dr. X, 9/21/2012, at 10:30 am.
Synoptic Reporting

- Ensure completeness BUT not necessarily accuracy
Pathology M and M Rounds

• Review of all errors, near misses, diagnostic challenges
• Done in a generally blinded way to encourage participation
• Educational
Safety Committee

• Members are not division leaders or directors
• Selected from practicing members
• May have ad hoc members
• Review critical safety events and make recommendations
• Formal process
• Meets as required
In the setting of an adverse event in health care, full disclosure and transparency is a moral and ethical mandate, despite caregivers' competing interests and malpractice liability concerns.

The vast majority of patients wish to be informed of adverse events and medical errors.

Failure to acknowledge or disclose a serious error can be very distressing for patients and is a powerful stimulus for complaint and litigation.

Response to a serious incident:
- Minimize harm
- Protect evidence
- Promptly inform healthcare team
- Promptly inform patient and offer support
- Document all these actions on medical record.

When to inform patients about errors:
- Minor errors: **NO**
- Near miss: Depends
- Serious errors: **YES**

This report extensively guides communication with patients, reporting and follow-up, but nothing relevant to pathologists.
Error or discrepancy identified

Internal reporting, documentation and resolution, per established policies

Is it relevant for patient care?

1. Is it relevant for patient care?
   - No disclosure on the pathology report

2. Full transparency on the pathology report, with wording consistent with a proactive safety culture, including:
   - Accurate description or error/discrepancy (wording!).
   - Communication with clinical team.
   - Peer review / QA initiated.
   - Conclusions and recommendations.
1. **Internal reporting, resolution and documentation of errors and discrepancies**

### Reporting and resolution

Mainly the **responsibility** of the assigned pathologist. May require communication with:

- Medical technologist
- Lab director
- Lab supervisor
- Peers
- Senior leadership
- Clinical team

### Documentation

**QUALITY ASSURANCE FORMS!!!**

Should be enforced by the lab director or designee (for laboratory tests) or the leadership (for pathology reports).

Should follow an established quality assurance process.
2. Is the error or discrepancy potentially relevant for patient care?

Not relevant for patient care

- Floater not belonging to patient sample (pathologist interpretation).
- Mislabelled slide identified and resolved.
- Lost block on a benign resection which does not affect pathology interpretation.
- Uninterpretable findings due to technical or clerical error, where a complete interpretation is already made on an alternative specimen.
- Almost any near miss, resolved before issuing any interpretation.

Potentially relevant for patient care

- Unexpected low recovery of tissue during processing ("lost during processing"), precluding complete diagnosis, classification or risk assessment.
- Any correction of the diagnosis, classification or risk assessment after issuing an interpretation (preliminary or formal).
- Discrepancy or disagreement on the diagnosis, classification or risk assessment by outside peer review.
- Floater vs. patient tissue, of potential clinical relevance, unresolved.
- Ancillary test (molecular, cytogenetic or otherwise), not concordant or discrepant with rendered diagnosis.
3. Reporting errors or discrepancies with full transparency and consistent with a proactive safety culture

Full Transparency

1. Accurate description or error/discrepancy (wording!).

2. Communication with clinical team.

3. Peer review / QA initiated.


- There was an unexpected low recovery of tissue during processing, precluding further studies and final classification. Dr. Smith was informed about the limitations of this specimen on 01/02/2014. A quality assurance process was initiated regarding these unforeseen circumstances. If clinically indicated, re-biopsy of the same site should allow for complete work-up and final classification.

- A corrected report is issued to change the diagnosis from “malignant neoplasm of undetermined origin, see Comment” to “malignant histiocytic neoplasm, see Comment”, based on an outside review of this material issued by MD. Anderson Cancer Center (Houston, TX) on 12/13/2015, and additional studies performed at H. Lee Moffitt Cancer Center (see Comment for details). This case was reviewed at the Intradepartmental Consensus Conference on 01/11/2016, in agreement with the above change in diagnosis. Dr. Clarkson was informed in this change in diagnosis on 01/13/2016.

- An addendum report is issued to Comment on the results from gene expression analysis (“tissue of origin”). The diagnosis remains unchanged. “Tissue of origin” analysis performed by CGI was reported as “neoplasm of likely melanocytic origin” (see separate report). This case was reviewed with Dr. Bui and Dr. Centeno, who agree with the original diagnosis of “malignant fibrous histiocytoma” (see Comment below for discussion of “tissue of origin”’s These results were discussed with Dr. House on 02/12/2014.
AP Quality Assurance Meeting

2015

September Key pathology Indicators
Corrected Reports – SP Cases

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Total Cases 2014:
- 3957
- 4189
- 3897
- 3872
- 3963
- 3897
- 3727
- 4331
- 3651
- 4259
- 39743

Total Cases 2015:
- 3912
- 2926
- 2738
- 2946
- 2611
- 2824
- 2812
- 2776
- 2706
- 25030

Variance:
- #DIV/0!

% Error All Types:
- 0.9%
- 0.9%
- 0.7%
- 1.1%
- 1.0%
- 0.8%
- 1.3%
- 0.7%
- 1.0%
- #DIV/0!

% Error CD-SM:
- 0.15%
- 0.10%
- 0.22%
- 0.17%
- 0.08%
- 0.21%
- 0.57%
- 0.14%
- 0.07%
- #DIV/0!

Arch Pathol Lab Med – Vol 129, Oct 2005
Error Detection in Anatomic Pathology
Richard J. Zarbo, MD, DMD; Frederick A. Meier, MSCM; Stephen S. Raab, MD

0.1% Error Rate – 5000 SP cases - Retrospective blinded review

CD = Change Diagnosis; SCI = Change Same Category of Interpretation; MS = Change in Margin Status; LN = Change in Lymph Node Status; IUTD = Information Unrelated to Diagnosis; PM = Case/Patient Misidentification; SM = Site Misidentification;
Synoptic Use Audit – Sep 2015
Frozen vs. Final Specimens

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</tr>
<tr>
<td>No. of (+) Cases</td>
<td>132</td>
</tr>
<tr>
<td>In Report (+) Cases</td>
<td>92%</td>
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Compliance:
- ≥90
- 60-80
- <60

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Total: 132, Compliance: 92%
## Case Correlation Events

### Total Cases

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<tr>
<th>Count of Resolution Program</th>
<th>Final Discrepancy</th>
<th>Major</th>
<th>Minor</th>
<th>Total</th>
<th>Program % Discordant</th>
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<td>Head and Neck</td>
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### RV, RC, RG Cases

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<th>Minor</th>
<th>Total</th>
<th>Program % Discordant</th>
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<tbody>
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<td>Breast</td>
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<td>134</td>
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<td>151</td>
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<tr>
<td>Cytopathology</td>
<td>Major</td>
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Occurrence Reports September 2015

1 Hospital Occurrence Reports:
- 14 Sep 15 – GU “sent” 3 urine samples for cyto; orders cancelled. Orders cancelled after 7 days by the system. Specimens never received in lab.

3 Laboratory Occurrence Reports:
- Case did not display dx correlation for Frozen vs Final. IT ticket submitted/organ added.
- Consult slides received were on wrong pt and not discovered until during review. Called contributor and correct slides received next day.
- 2 cases switched. Grossing policy reinforced to PAs.
Informatics

Essential to monitor practice
Development of key performance metrics
Very difficult
Moffitt information system not designed for extracting high granularity quality information
Able to use to build “must complete” tasks for pathologists
Tools for the FUTURE

Total Quality Management
Improved informatics and real time data
Telepathology – access to experts and artificial intelligence and advanced imaging
Improved molecular diagnostics also blood based liquid biopsy methods
Incentivization of quality and value
Training and education
Development and access to best in class experts and networks
Summary

• Measuring quality metrics is becoming increasingly important in the current healthcare environment
• A number of practices have been recommended to reduce error in AP
• Further standardization and measurement is needed.