117 Applying Risk Management Principles to QA in Surgical Pathology: From Principles to Practice

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This session will emphasize, through real world examples, the importance of risk management to surgical pathology.

- The concepts of risk management will be reviewed and participants will be provided with the tools to estimate the risk and consequences of potential hazardous situations in surgical pathology.
- Participants will learn how to apply estimates of risk and criticality of outcomes in a simple formula to guide the introduction of concurrent and retrospective reviews.
- Case study material will be used to demonstrate the cost and benefits of the risk management approach as compared with current practices.

FACULTY:

Gregory Flynn MD

Practicing Pathologists
Practice and Quality Management

1.0 CME/CMLE Credit

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Applying Risk Management Principles to QA in Surgical Pathology: From Principles to Practice

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Managing Director, Quality Management Program—Laboratory Services

Disclosure Statement
I do not have any financial interest or affiliation with any organization that may cause conflict of interest pertaining to content of this presentation.

- What errors or hazards can occur?
- How severe can they be?
- How frequent can they be?
- What precautions should be taken for reducing the risk?
Risk management techniques present us with systematic ways to search for the error-prone processes.

Risk Management

- Present systematic ways to search for the error-prone processes
- Focuses on potential and observed adverse events
- Determine:
  - The weak points in the processes
  - Their probability of causing errors
  - The estimating the impact of the error
- Final aim is to identify risky situations and giving prioritization to prevent occurrence of the adverse events
Steps in a RCA Investigation

- Definition of the problem
- Identification of the critical steps
- Identification of root causes
- Evidences for root causes
- Identification of solutions
- Development of recommendations
Can we develop a risk management tool for the selection of pathology cases that need to be sent for second review?

Methodology 1

Literature was critically reviewed for assessment of:

1. Error rates
2. Causes of errors (focus was on interpretation of errors)

Methodology 2

1. Error Rates:
   - Journal articles presenting error rates in surgical pathology based on second opinion were selected.
   - Errors were re-classified as catastrophic, major, moderate and minor.
   - Articles containing incomplete information for this re-classification were excluded from the study.
   - Discrepancy frequency was calculated for the aggregate data (100\* number of discrepancy/ total number of cases)

2. Causes of Errors (focus was on interpretation errors)
Variables could affect published error rates

- Research designs
- Definition of discrepancy/error
- Method of case selection
- Tissue type

Error detection methods in Pathology

<table>
<thead>
<tr>
<th>Single institution studies</th>
<th>Multi-institutional studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Second opinion:</td>
<td>Surveys</td>
</tr>
<tr>
<td>- Double reader no specialized skills</td>
<td></td>
</tr>
<tr>
<td>- Double reader specialized skills</td>
<td></td>
</tr>
<tr>
<td>- Conference review</td>
<td>- Databases</td>
</tr>
<tr>
<td>- Institutional review</td>
<td></td>
</tr>
<tr>
<td>Correlation review</td>
<td>Virtual microscopy</td>
</tr>
<tr>
<td>- Cytology - histology correlation</td>
<td></td>
</tr>
<tr>
<td>- Frozen section - histology correlation</td>
<td></td>
</tr>
<tr>
<td>- Virtual microscopy</td>
<td></td>
</tr>
<tr>
<td>External quality assessment</td>
<td></td>
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</tbody>
</table>

Sources of Errors

- Accessioning errors
- Grossing errors
- Histology tissue processing
- Transcription errors
- Ancillary testing errors
- Interpretation errors
- Reporting errors

Heterogeneity of research designs and error classification

- Lack of gold standard for error detection
- Selection of cases
- Error detection methods
- Type of second opinion
- Classification of errors


Heterogeneity of research designs and error classification

- Lack of gold standard for error detection
  - Second reviewer’s diagnosis is assumed to be gold standard
  - Clinical and pathologic outcome (most studies do not include)
- Selection of cases
  - Random
  - Pseudo random
- Error detection methods
  - Blind review
  - Focused review
  - Review of referral cases
  - Cytology histology correlation
  - Clinician driven review
  - Amended report review
  - Type of second opinion
  - Expert
  - Non-expert
  - Expert center
  - Consultation
  - Conference (e.g., tumor board, subspecialty, difficult case conferences)
- Classification of errors
  (Lack of standard way of reporting errors makes it difficult to compare results from different studies.)
  - False positive, false negative
  - Threshold (differences in opinion), differences in grade and type
  - Major and minor
  - Pre-analytic, analytic and post-analytic


Definitions of errors and their severity

<table>
<thead>
<tr>
<th>Category</th>
<th>Definitions</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>Multiple, consistent (precise) major harm</td>
<td>All end result IHC (like FISH or oestrogen receptor) results are false negative or false positive because of systematic error</td>
</tr>
<tr>
<td>Major</td>
<td>Irreversible major clinical harm</td>
<td>Erroneous patient management leading to loss of life, limb, or organ</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderate clinical harm, correct is not easy but possible</td>
<td>Tumour grading errors which affects treatment</td>
</tr>
<tr>
<td>Minor</td>
<td>Minor harm, easily amendable</td>
<td>Same treatment, different prognosis or pertinent information not included</td>
</tr>
<tr>
<td>Near Miss</td>
<td>Near misses (system or guideline has step and control points, harm is easily avoidable)</td>
<td>Evaluating more than one specimen from same patient can correct possible error</td>
</tr>
</tbody>
</table>
### Error rates (referral cases)

<table>
<thead>
<tr>
<th>No. of Journal Articles</th>
<th>Total No. of Cases</th>
<th>Median Discrepancy % (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Agreement</td>
</tr>
</tbody>
</table>

- **No. of Journal Articles: 30**
- **Total No. of Cases: 22340**
- **Median Discrepancy % (Range):**
  - Total: 22.6 (5.4–53.5)
  - Major: 4.4 (0–24.4)
  - Moderate: 6.2 (0–27.7)
  - Minor: 8.5 (0–53.3)
  - Agreement: 77.2 (46.7–94.6)

### Relationship between discrepancy rates and type of second opinion

<table>
<thead>
<tr>
<th>Second Opinion</th>
<th>Total No. of Cases</th>
<th>Median Discrepancy % (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total D*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major D*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate D*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minor D*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No D*</td>
</tr>
<tr>
<td>Expert (n=14)</td>
<td>11090</td>
<td>(10.9–43.8)</td>
</tr>
<tr>
<td>Academic/Cancer</td>
<td>3436</td>
<td>(6.6–53.3)</td>
</tr>
<tr>
<td>Center (null)</td>
<td>23.4</td>
<td>(0.0–20.4)</td>
</tr>
<tr>
<td>Non-expert (n=8)</td>
<td>7814</td>
<td>(0.0–53.3)</td>
</tr>
</tbody>
</table>

* Discrepancy

**P values: >0.05**

Mann-Whitney U-test were used for the comparison of median values obtained in subgroups.

### Blinded Review

**Advantages**
- Free from bias
- It can be applied all cases (consultation rarely applied on negative cases, so false negative cases are rarely recognized)

**Disadvantages**
- For some types of tissues, impossible to diagnose without knowing clinical presentation (e.g. bone biopsies)
- Review is generally performed faster than initial examination, sensitivity does not 100%
Blinded Review

<table>
<thead>
<tr>
<th>Total No. of Cases</th>
<th>Total D* (%)</th>
<th>False negatives (%)</th>
<th>Agreement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>23250</td>
<td>7.38</td>
<td>0.24</td>
<td>92.62</td>
</tr>
</tbody>
</table>

* Discrepancy

- Risk of major error in referral cases: 4.4%
- Risk of occurrence of major or moderate errors in referral cases: 10.6%
- Risk of false negative errors in blinded reviews: 0.24%.

Review of literature indicates

- 416 cases should be reviewed for identification of one false negative error.

It is necessary to develop a strategy for selection of cases that need to be sent for second review.
Value of Second Review

<table>
<thead>
<tr>
<th>No. of Pathologist on First Report</th>
<th>No. of Cases</th>
<th>Disagreements (%)</th>
<th>Amendments (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7276</td>
<td>7.2</td>
<td>0.5</td>
</tr>
<tr>
<td>≥2</td>
<td>1087</td>
<td>4.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>8363</td>
<td>6.9</td>
<td>0.4</td>
</tr>
<tr>
<td>p</td>
<td>0.004</td>
<td>0.12</td>
<td></td>
</tr>
</tbody>
</table>

Intra-departmental second review of cases lower disagreement in subsequent blinded review.

Q: How do we determine cases that need to be sent for a second opinion?

**One option**

Sending all neoplasia cases to second review.

- Some neoplasia can be easily diagnosed – second opinion is not necessary.
- False negatives cannot be identified.
- Non-neoplastic difficult cases, such as infection and atypia are not reviewed.

Renshaw proposed to review “all cases that appear to be difficult.”

Root causes of discrepancies (errors)

<table>
<thead>
<tr>
<th>No fault</th>
<th>Systemic</th>
<th>Cognitive</th>
</tr>
</thead>
<tbody>
<tr>
<td>New tumour classification or different grading system</td>
<td>Systematic errors in ancillary tests (e.g., IHC)</td>
<td>Data interpretation</td>
</tr>
<tr>
<td>New diagnostic criteria</td>
<td>Problems associated with histological stain or technique</td>
<td>Reasoning</td>
</tr>
<tr>
<td>Unexpected presentation</td>
<td>No system to confirm patient ID or sample</td>
<td>Knowledge related</td>
</tr>
<tr>
<td>Tissue or cytological sample is not representative for a lesion</td>
<td>Long turnaround times</td>
<td></td>
</tr>
</tbody>
</table>
No fault – as a discrepancy cause

Murphy et. al. (2002) evaluated

- Inter-observer discrepancy
- WHO/International Society of Urologic Pathology Classification of Urothelial Neoplasms

No fault – as a discrepancy cause

Discrimination of:
Low malignant potential papillary uroepithelial neoplasm
AND
Low grade papillary uroepithelial carcinoma

Discrepancy rate:
before education: 50%
after education: 39%

Papillary urothelial neoplasm of low malignant potential
AND
High grade carcinoma or carcinoma in situ.

No discrepancies

After eliminating categories with poor reproducibility

Discrepancy rate: 10%

No fault – as a discrepancy cause

- Diagnostic and prognostic classifications affects discrimination rates
- Morphological similarity among categories increases the interpretive discrepancy
Cognitive Error Types

- Anchoring
- Confirmation bias
- Expectation bias
- Semmelweis effect
- Availability of heuristics
- Premature closure
- Over confidence
- Change blindness

Overconfidence

“Miscalibration of one’s own sense of accuracy”

- 1% of drivers rate their skills below that of the average driver.
- 94% of academic professionals rate themselves in the top half of their profession.

Overconfidence as a cause of diagnostic error in medicine, Am J Med 2008: 121 S2-S23

Overconfidence

- Physicians’ confidence levels in case scenarios
  - Medical students: least accurate and least confident
  - Attending physicians: most accurate and highly confident
  - Residents: more confident, but less accurate
- Board certified radiologists
  - Confidence level of the worst performers were higher than the best performers

Overconfidence as a cause of diagnostic error in medicine, Am J Med 2008: 121 S2-S23
Pathology interpretation errors may arise from multiple causes

1. Lack of knowledge
2. Cognitive Errors
3. Lack of well established diagnostic criteria
4. Inter- and intra-observer discrepancy
5. Lack of adequate clinical information
6. Clinician’s interpretation
7. Lack of expertise
8. Lack of experience
9. (New methods are riskier than older methods)

Suggestion 1:

Use of Sign-out Checklist

- Filled by the pathologist just before sending out the reports
- This checklist prepared based on previously published literature on causes of discrepancies in pathology laboratories and misdiagnosis in medicine general.
Conscious review of subconscious processing may prevent biases and errors.

- Medical decisions are made in the “adaptive unconscious”
- Cognitive errors arise in “synthesis step of diagnostic process”
- Synthesis step is mainly unconscious and habitual

Benefits of checklists

1. Provide tool for selection of the cases for second opinion.
2. Help pathologist to evaluate her/his risk of making incorrect decision in a particular specimen, and select cases for second review.
3. Give pathologist a chance to self-assesses her/his decision making process, just before sending the report.
4. Might be a tool for improving the match between pathologists self-claimed confidence levels and actual errors in long term.
Suggestion 2: Disclosing Uncertainty

- Measurement uncertainty concept is introduced in medical testing, but not interpretive tests like surgical pathology.
- Not because pathology test results do not bear uncertainty, but lack of method for determination of uncertainty.

Bryant SJ and Davies DJ, "Diagnostic error in anatomical pathology: the uncertainty of its measurement?" Pathology (December 2006) 38(6), pp. 487-9

Measured HbA1c (%) | Uncertainty of Measurement range for and analytical CV of 3% (95% confidence levels)
--- | ---
6.5 | 6.1 - 6.9
7.0 | 6.6 - 7.4
7.5 | 7.1 - 8.0

Uncertainty

- In current practice, histopathology results are considered as absolute truth.
- Introducing “measurement uncertainty” in histopathology decreases unrealistic expectations, and protects pathologist from excessive demands.

Reporting risk of malignancy

Renshaw:
Reporting a quantitative risk for malignancy or dysplasia for cytological screening tests

Risk values can be obtained from:
• Literature,
• Individual laboratory and
• Individual cytologist

Reporting Uncertainty

University of Colorado Health Sciences Center adds a note to the report:
“This is a difficult case.”

- This approach
  - Inform physician and patients about necessity of considering other differential diagnosis.
Reporting diagnostic certainty in a scale of 1–5

1. Uncertain
2. Somewhat uncertain
3. Neither certain nor uncertain
4. Somewhat certain
5. Certain

Sign-out checklist and published literature can be used in determining uncertainty.

Thank you

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