Disclosure/Communication of Laboratory Errors

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Goals and Agenda

• At the end of the presentation, participants should be able to:
  • 1. document errors in the context of a quality assurance program,
  • 2. determine the appropriate way to correct errors in the medical record,
  • 3. determine which error should be communicated to caring physicians and patients.
Background

• Laboratory Errors are common.
• When errors are discovered, how should they be addressed?
• This presentation will examine appropriate policies and procedures to manage errors.
Clinical Chemistry

- Arch Pathol Lab Med 2004;128:890-892
- Corrected results
- 187/72791 (0.26%)
- 17% pre, 25% analytic, 59% post
- Pre-analytic error led to redraw
- Analytic errors led to reanalysis of specimen
- Post analytic errors led to correction
Microbiology

- J Clin Microbiol 2005;43:2188-2193
- Corrected results impact
- 408/164000 (0.3%) (2003-2004)
- 32 (6.7%) associated with adverse clinical outcome
- 31 analytic, 1 Post analytic
- Delayed or inappropriate or unnecessary Rx
Surgical Pathology

• Adv Anat Pathol 2011;18:406-413
• Amended reports
  • Misidentification, Specimen defects, Misinterpretation, report defects
• Described in the contexts of other quality improvement initiatives
## Monitoring Defect Fractions

<table>
<thead>
<tr>
<th></th>
<th>Amend Reports (per 1000)</th>
<th>Mis-ID # (% of total)</th>
<th>Sp Defects # (% of total)</th>
<th>Mis-Interp # (% of total)</th>
<th>Rp Defects # (% of total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>10.1</td>
<td>74 (15.6)</td>
<td>9 (1.9)</td>
<td>87 (18.3)</td>
<td>305 (64.2)</td>
</tr>
<tr>
<td>2006</td>
<td>7.8</td>
<td>46 (12.3)</td>
<td>16 (4.3)</td>
<td>59 (15.8)</td>
<td>253 (67.6)</td>
</tr>
<tr>
<td>2007</td>
<td>6.3</td>
<td>38 (12.0)</td>
<td>33 (11.0)</td>
<td>22 (7.0)</td>
<td>213 (70.0)</td>
</tr>
<tr>
<td>2008</td>
<td>5.6</td>
<td>24 (8.7)</td>
<td>13 (5)</td>
<td>8 (3.0)</td>
<td>229 (83.0)</td>
</tr>
</tbody>
</table>
## Impact on Patient Care

<table>
<thead>
<tr>
<th></th>
<th>Corrections</th>
<th>Some harm</th>
<th>Serious harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Pathology</td>
<td>5.1 %</td>
<td>16.6%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Microbiology</td>
<td>0.3%</td>
<td>6.7%</td>
<td></td>
</tr>
<tr>
<td>Chemistry</td>
<td>0.26 to 0.01%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Adverse Outcome

- Delayed therapy
- Unnecessary therapy changes
- Inappropriate therapy
- Unnecessary increase level of care
Policy and Procedure

• Define a procedure for correcting results
• Record changes in QA log
• Document incident reports in accordance with policy
  • Changes that affect patient care
Procedures for Correcting Report Errors

• Prompt correction is recommended
• Inform ordering provider as well as other caregivers
• Many consider corrected reports a critical value that should be communicated directly
• No requirement for explanation of how error occurred
• Must maintain original report as well as corrected or amended report within pathology
Policy and Procedure

• Procedure for paper reports
  • Clearly mark original report as being in error
  • Clearly mark the new report as a corrected report

• Procedure for electronic reports
  • Clearly mark the result as corrected
  • Include notes to explain the change and clearly date and document the changes
Procedures for Correcting Report Errors

• Mark the report as “corrected”, “amended” or “revised”

• Numeric corrections may be flagged with a footnote that clearly identifies the result as corrected.

• The term “addendum” should not be use in which there is a change in the diagnostic information. “Addendum” should only be used when additional information is conveyed without any changes to existing results.
Formatting of Corrected reports

• The previous result should NOT be repeated near the corrected result.

• The corrected result should be clearly indicated as corrected.

• The original report should be maintained in pathology but with the corrected report.

• In the electronic record, the original report should be retain but not easily accessible.
## Glucose Result

<table>
<thead>
<tr>
<th>Result</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canceled</td>
<td>Canceled</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1</td>
<td>669 * C (c)</td>
</tr>
<tr>
<td>3.9</td>
<td>265 H</td>
</tr>
<tr>
<td>3.5</td>
<td>134 H</td>
</tr>
</tbody>
</table>

582 * C

>600 * C

124 * H

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1.) (Medium Importance) Result Comment by Contributor
24-Aug-2013 08:21 EDT
Glucose CORRECTED FROM 15 ON 08/24/2013

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RESULT phoned at 08/24/13 08:11 by m072043.
Result accepted and read back by  

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Bone Marrow Result

**DDENDUM DIAGNOSIS**
*CORRECTED REPORT – NO CHANGE IN DIAGNOSIS***
Report corrected due to typographical error.

**TEST PERFORMED:** B-Cell Lymphoma, FISH, B/BM

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Result (%)</th>
<th>95% normal cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>(11;14)(CCND1/IGH)</td>
<td>abnormal (4.6%)</td>
<td>&lt;0.6</td>
</tr>
</tbody>
</table>

**NOMENCLATURE:** nuc ish(CCND1-XTx3),(IGHx3),(CCND1-XT con IGHx2)[23/500]

**Interpretation:** The result is abnormal and indicates CCND1/IGH fusion *(11;14) in 4.6% of nuclei.
Surgical Pathology Report

FINAL DIAGNOSIS
***REVISED DIAGNOSIS***

Previously reported diagnosis has been changed due to typographical errors. Please review the amended report below.

A, B, C, D, G, I) Lung, right upper lobe, wedges #1-5 and nodule #2: Resection: Metastatic spindle cell sarcoma, histologically similar to synovial sarcoma (SP-13-3886) with surgical margins free of tumor.
Investigating the Cause of Lab Error

• All erroneous report should be treated as an incident and investigated.

• If a systemic cause of error is found this should be addressed

• Systems should undergo periodic appraisal for effectiveness

• Many AP and CP labs have standing monitors to document and evaluate amended or corrected reports.
## Q-Tracks Study

<table>
<thead>
<tr>
<th>Year</th>
<th>n</th>
<th>10th</th>
<th>50th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>91</td>
<td>1.2</td>
<td>5.2</td>
<td>11.5</td>
</tr>
<tr>
<td>2007</td>
<td>92</td>
<td>1.3</td>
<td>3.7</td>
<td>10.9</td>
</tr>
<tr>
<td>2008</td>
<td>92</td>
<td>1.3</td>
<td>4.1</td>
<td>13.7</td>
</tr>
<tr>
<td>2009</td>
<td>93</td>
<td>1.5</td>
<td>3.9</td>
<td>11.4</td>
</tr>
<tr>
<td>2010</td>
<td>87</td>
<td>0.9</td>
<td>3.3</td>
<td>14.5</td>
</tr>
<tr>
<td>2011</td>
<td>82</td>
<td>0.8</td>
<td>2.7</td>
<td>9.1</td>
</tr>
</tbody>
</table>

Percentile rate of corrected reports per 10,000
What mechanism of disclosure should be used?

• Many choices
  • Documentation in a QA log
  • Documentation with investigation (root cause analysis)
  • Disclosure to an institutional body (hospital)
  • Disclosure to the patient
Types of Error

• Mislabeled specimen, corrected at the bed side
  • Documentation in a QA log
  • Documentation with investigation (root cause analysis)
  • Disclosure to an institutional body (hospital)
  • Disclosure to the patient
Types of Error

- Mislabeled specimen with report issued on the wrong patient with NO patient harm
  - Documentation in a QA log
  - Documentation with investigation (root cause analysis)
- Disclosure to an institutional body (hospital)
- Disclosure to the patient
Types of Error

• Mislabeled specimen with report issued on the wrong patient with surgery performed on the wrong patient
  • Documentation in a QA log
  • Documentation with investigation (root cause analysis)
• Disclosure to an institutional body (hospital)
• Disclosure to the patient
## Error Response

<table>
<thead>
<tr>
<th></th>
<th>Minimal</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quick discovery</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Intermediate discovery</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Long term discovery</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
Disclosure

- Ethical obligation to disclose harmful and clinically significant medical errors to patients
- Pathologist does not usually have a working relationship with patients
- Pathologists usually work through another care giver, (surgeon, oncologist, etc)
- Work with the other care giver
  - Some will want pathologists present
  - Some will not
Communication Pathology and Laboratory Errors


• Survey of 260 anatomic pathologists and 81 laboratory medical directors

• July – December 2008

• Questions:
  • Estimated error rates and barriers to disclosure
  • Awareness of reporting system
  • Error disclosure
<table>
<thead>
<tr>
<th></th>
<th>Anatomic Pathol</th>
<th>Clinical Pathol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formal Reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incident reporting</td>
<td>54%</td>
<td>86%</td>
</tr>
<tr>
<td>Risk management</td>
<td>59.3%</td>
<td>43%</td>
</tr>
<tr>
<td>Patient Safety Program</td>
<td>20.7%</td>
<td></td>
</tr>
<tr>
<td>Informal reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supervisor</td>
<td>40.2%</td>
<td></td>
</tr>
<tr>
<td>Chief or Chair</td>
<td>47.9%</td>
<td></td>
</tr>
<tr>
<td>CEO</td>
<td>16%</td>
<td></td>
</tr>
</tbody>
</table>

Dintzis, et al

- Factors that may deter disclosing serious errors (n = 169)
  - 49.7% “I think the patient would not understand what he or she was being told
  - 40.2% “I think the physicians would not be able to explain the error clearly to the patient
  - 11.2% “I think the patient would not want to know about the error
  - 11.2% “The patient is unaware that the error happened.
<table>
<thead>
<tr>
<th>Involvement with Medical Error</th>
<th>Pathologist and Lab Directors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Near miss</td>
<td>77.6 %</td>
</tr>
<tr>
<td>Minor error</td>
<td>69.1 %</td>
</tr>
<tr>
<td>Serious error</td>
<td>43.6 %</td>
</tr>
<tr>
<td>None</td>
<td>4.8 %</td>
</tr>
<tr>
<td>Disclose serious error to patient</td>
<td>16.2 %</td>
</tr>
<tr>
<td>Disclose minor error to patient</td>
<td>5.5 %</td>
</tr>
<tr>
<td>Statement</td>
<td>Pathologist and Lab Directors</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Near miss should be disclosed to patient</td>
<td>20.1%</td>
</tr>
<tr>
<td>Minor error should be disclosed to patient</td>
<td>72.3%</td>
</tr>
<tr>
<td>Serious error should be disclosed to patient</td>
<td>97.0%</td>
</tr>
<tr>
<td>Near miss should be reported to Hospital/HMO</td>
<td>60.5%</td>
</tr>
<tr>
<td>Minor error should be reported to Hospital/HMO</td>
<td>76.0%</td>
</tr>
<tr>
<td>Serious error should be reported to Hospital/HMO</td>
<td>94.6%</td>
</tr>
</tbody>
</table>

Concerns

- 24.7% did not know about reporting system
- 28.2% of AP stated system unavailable to them
- AP most often reported to risk management (59.3%)
- Lab directors used incident reporting system (85.7%)
- 47.8% stated current system adequate
Satisfaction with Disclosure

• 22 of 25 (88%) who disclosed directly to patients reported satisfaction with the results

• Of those that reported minor errors directly to patients 11 of 12 (91.7%) reported satisfaction with the disclosure

• 88.6% have interest in education on disclosure

• Only 21.6 had received any education
Apologies

- Indirect relationship with patient
- Communicate and work with clinician
  - Good relationship offers the opportunity to apologize and explain directly to patient with support of clinician
  - Poor communication may lead to pathologists being blamed
Dewar et al

- Transcription error
  - Adenomyoma transcribed as Adenosarcoma
  - Quickly identified error
  - Apologized and offer financial settlement
  - Helped create closure and move forward

- Interpretive diagnostic error
  - Squamous cell Carcinoma diagnosed on evaluation at outside hospital
  - Pathologist was dismissive of the surgeon requesting help
  - Reflected badly on Pathologist and invites legal action
Dewar et al

- Early and complete disclosure and apology soften the blow of injury
- Consultation with risk management and clinical care team
- Should be done for errors that affect clinical care and management
- Teach in residency, to accept, analyze and apologize for errors
- System of Apology should be accepted and encourages by Department Chair and institution
Summary

- Errors and corrected reports are common in the laboratory
- Laboratories should have a system to correct reports and inform clinicians of these corrections
- There should be a method of monitoring errors and corrections within the laboratory
- Disclosing errors to patients is dependent on many factors including potential patient harm and a good working relationship with clinicians
Thank you!