Disclosure/Communication of Laboratory Errors

Raouf E Nakhleh, MD
Mayo Clinic Florida

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

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

Impact on Patient Care

	Corrections	Some harm	Serious harm
Surgical Pathology	5.1 %	16.6%	2.1%
Microbiology	0.3%	6.7%	
Chemistry	0.26 to 0.01%		

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

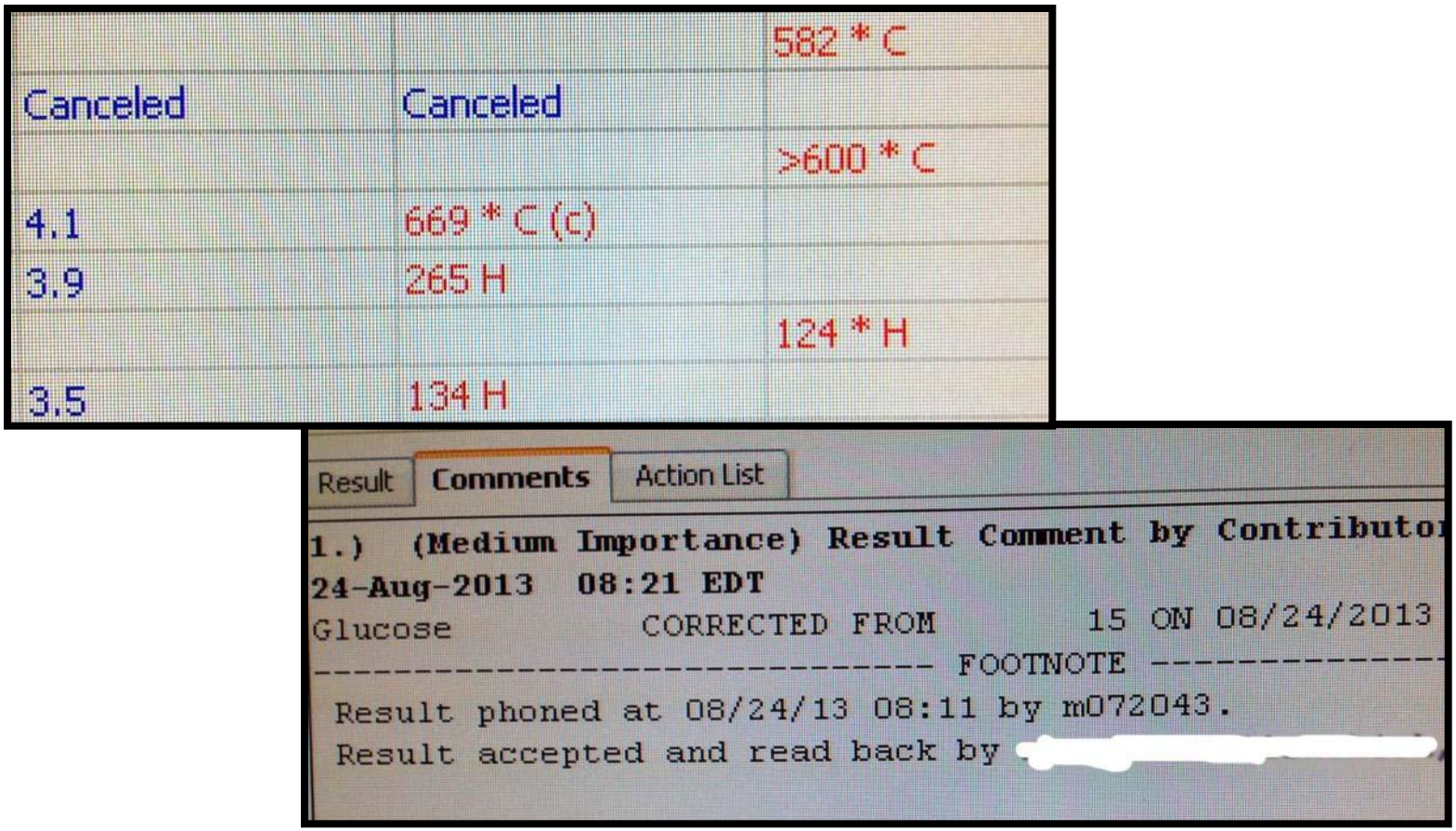
Procedures for Correcting Report Errors

- 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

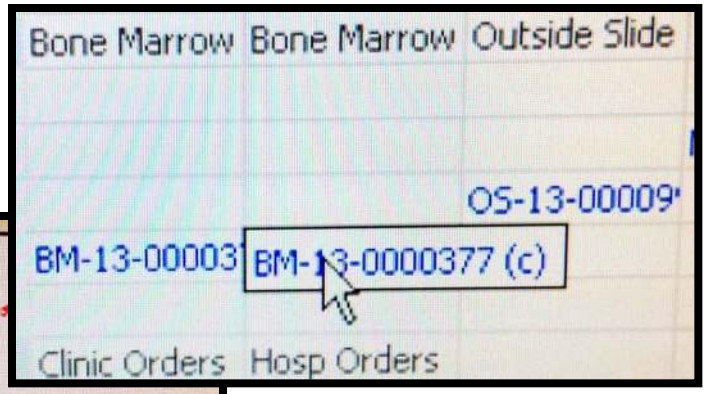


		582 * C
Canceled	Canceled	
		>600 * C
4.1	669 * C (c)	
3.9	265 H	
		124 * H
3.5	134 H	

Result | Comments | Action List

1.) (Medium Importance) Result Comment by Contributo
24-Aug-2013 08:21 EDT
Glucose CORRECTED FROM 15 ON 08/24/2013
---------- FOOTNOTE ----------
Result phoned at 08/24/13 08:11 by m072043.
Result accepted and read back by [redacted]

Bone Marrow Result



DDENDUM DIAGNOSIS

*CORRECTED REPORT – NO CHANGE IN DIAGNOSIS***

eport corrected due to typographical error.

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

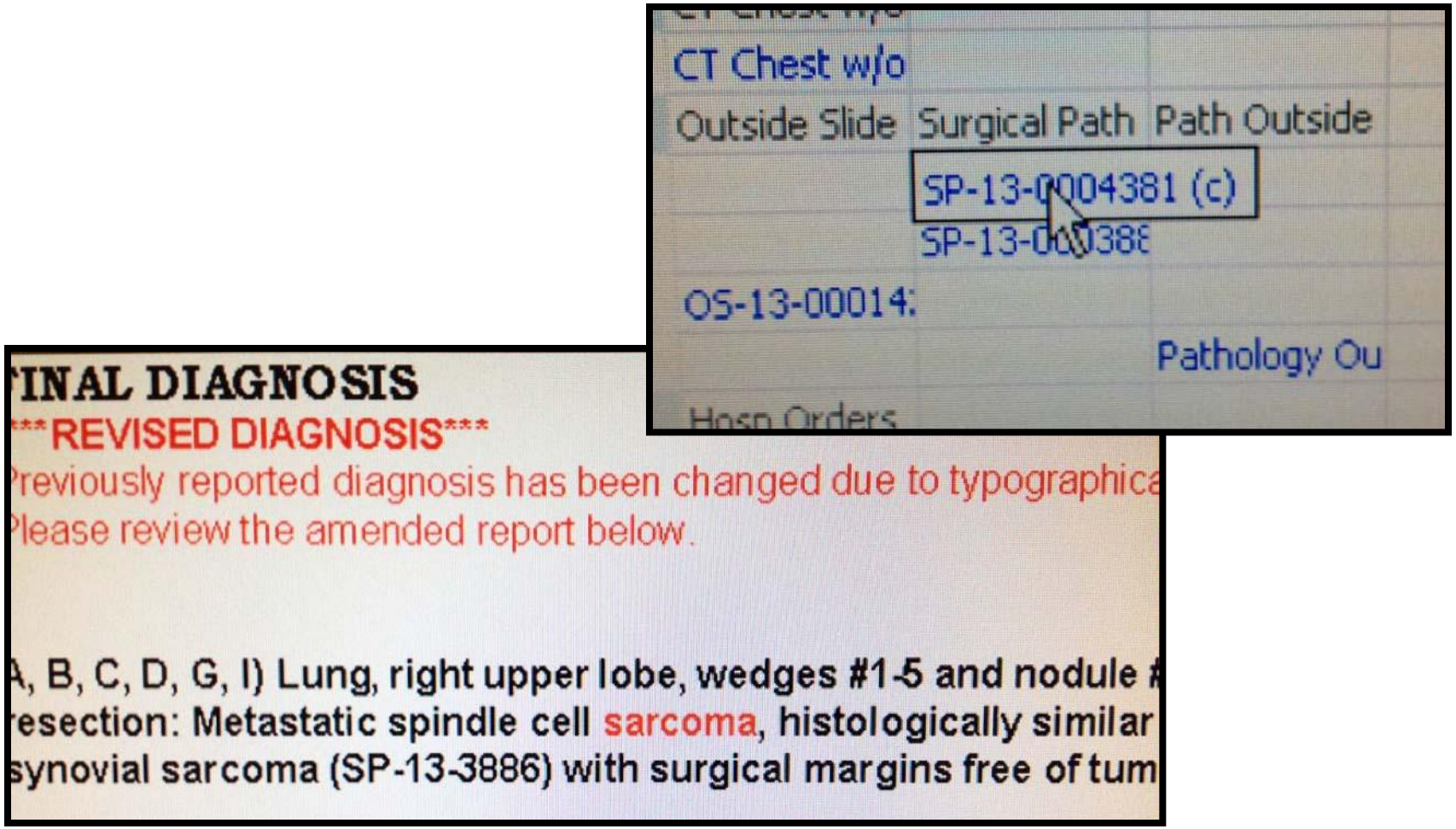
Result:

Abnormality	Result (%)	95% normal cutoff
(11;14)(CCND1/IGH)	abnormal (4.6%)	<0.6

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

Interpretation: The result is abnormal and indicates CCND1/IGH fusion.

Surgical Pathology Report

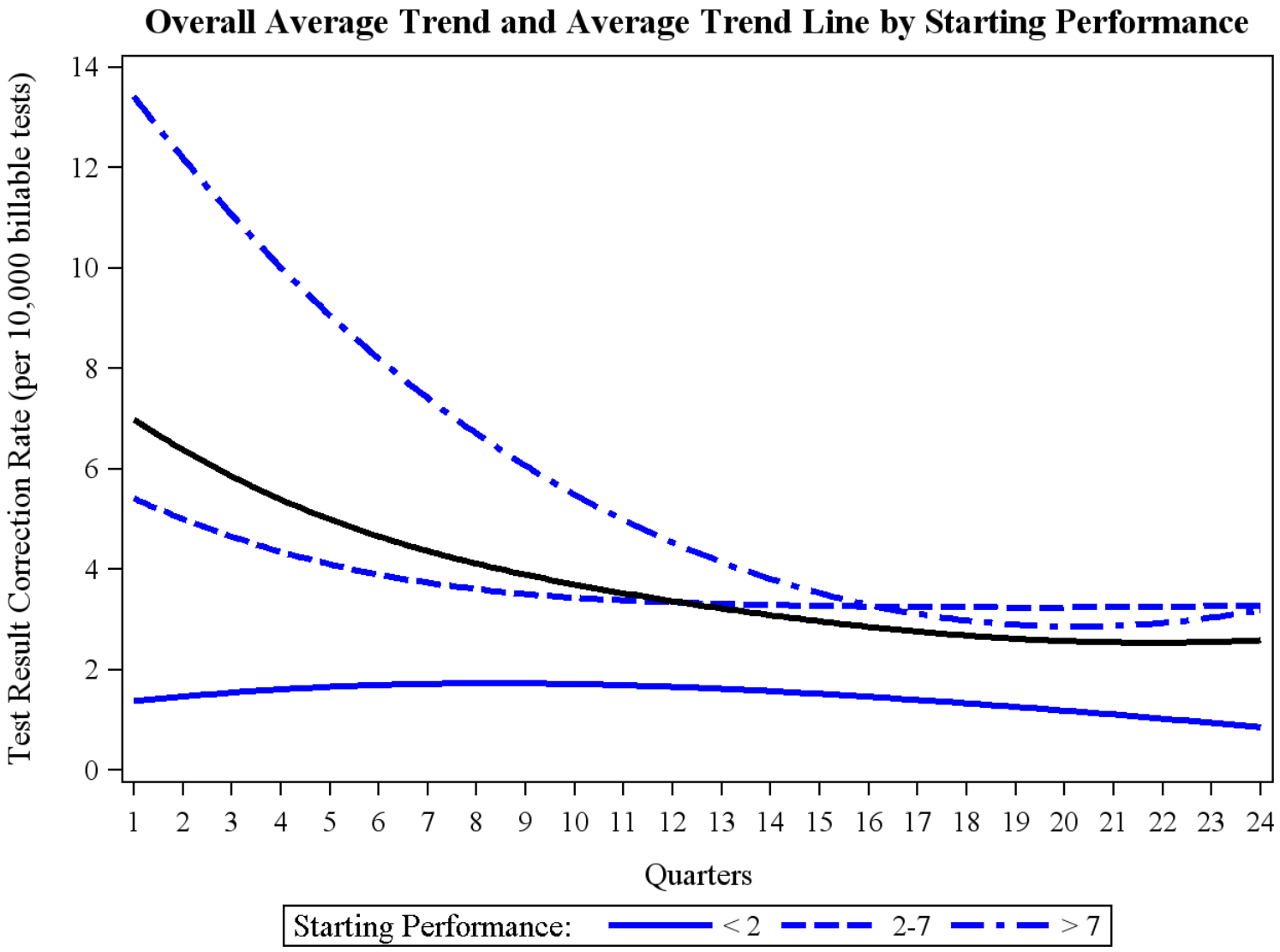


Investigating the Cause of Lab Error

- 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

Percentile rate of corrected reports per 10,000					
year		n	10th	50th	90th
	2006	91	1.2	5.2	11.5
	2007	92	1.3	3.7	10.9
	2008	92	1.3	4.1	13.7
	2009	93	1.5	3.9	11.4
	2010	87	0.9	3.3	14.5
	2011	82	0.8	2.7	9.1


Overall Average Trend and Average Trend Line by Starting Performance
Test Result Correction Rate (per 10,000 billable tests)
0
2
4
6
8
10
12
14
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
Quarters
Starting Performance: < 2 2-7 > 7

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

	Minimal	Significant
Quick discovery	?	?
Intermediate discovery	?	?
Long term discovery	?	?

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

- Dintzis, et al, Am J Clin Pathol 2011;135:760-765
- Suvey 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

	Anatomic Pathol	Clinical Pathol
Formal Reporting		
Incident reporting	54%	86%
Risk management	59.3%	43%
Patient Safety Program	20.7%	
Informal reporting		
Supervisor	40.2%	
Chief or Chair	47.9%	
CEO	16%	

Dintzis, et al, Am J Clin Pathol 2011;135:760-765

Dintzis, et al

- Factors that may deter disclosing serious errors (n =169)
  - 49.7% “I think the patent 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.

Involvement with Medical Error	Pathologist and Lab Directors
Near miss	77.6 %
Minor error	69.1 %
Serious error	43.6 %
None	4.8 %
Disclose serious error to patient	16.2 %
Disclose minor error to patient	5.5 %

Dintzis, et al, Am J Clin Pathol 2011;135:760-765

Statement	Pathologist and Lab Directors
Near miss should be disclosed to patient	20.1%
Minor error should be disclosed to patient	72.3%
Serious error should be disclosed to patient	97.0%
Near miss should be reported to Hospital/HMO	60.5%
Minor error should be reported to Hospital/HMO	76.0%
Serious error should be reported to Hospital/HMO	94.6%

Dintzis, et al, Am J Clin Pathol 2011;135:760-765

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

- Dewar et al, Int J of Surg Pathol 2013
- 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 correction
- 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!