

Error Prevention in Pathology

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Disclosers

- **Thank you**
 - **The Pathology Section of the Royal Academy of Medicine of Ireland**
 - **Faculty of Pathology, RCPI**
 - **Health Information and Quality Authority**
 - **Dr. Paul Crotty**
- **College of American Pathologists**
- **Mayo Clinic**

Overview

- **The U.S. experience**
- **Factors that lead to errors**
- **Error prevention Strategies**

IOM Report on Medical Errors

- **To Err is Human: Building a safer Health Care System**
 - **Published Dec 1, 1999**
 - **Epiphany**
 - **Outlined the problems**
 - **Offered solutions**

IOM Goals

- **Break “cycle of inaction” concerning patient safety and medical errors**
- **Enhance knowledge base about medical errors and develop tools**
- **Break down legal and cultural barriers that impede improvement**
- **Shift from blame for errors to prevention of errors**
- **Cause significant monetary investment**

IOM Strategies

- **Establish a national focus to create leadership, tools and protocols to enhance the knowledge base**
- **Enact tort reform**
- **Identify and learn from errors through mandatory and voluntary reporting systems**

IOM Strategies

- **Raise standards and expectations for improvement in safety through the actions of oversight organizations, group purchasers and professional groups.**
 - **Regulatory groups**
 - **Professional societies**
 - **Consumer groups**
 - **Employers.**

IOM Strategies

- **Use a systems approach to reduce medical errors and improve patient safety**

Response

- **Governmental**
 - **The Patient Safety and Quality Improvement act of 2005**
 - **National Medical Error Disclosure and Compensation Bill (MEDIC)**
 - **State and local initiatives**

The Patient Safety and Quality Improvement Act of 2005

- **Enable providers to contract voluntarily with patient safety organizations to help them:**
 - **Identify and analyze threats to patient safety and other quality problems**
 - **Improve health outcomes without fear that data will be disclosed or used in legal proceedings against them**
 - **Provide privilege and confidentiality to patient safety data without fear of legal implications**

National Medical Error Disclosure and Compensation Bill (MEDIC)

- **Promote open communication**
- **Reduce errors**
- **Ensure patients access to fair compensation for injury**
- **Reduce cost of medical liability**
- **Provide grant support and assistance to providers and fair compensation for injuries**

Accrediting Organizations

- **Joint Commission on Accreditation of Healthcare Organization (JCAHO)**
- **College of American Pathologist**

JCAHO

- **2001 revised standards to specifically address patient safety issues**
- **Including emphasis on disclosure of unanticipated outcomes and medical errors**
- **2003 National Patient Safety Goals**
- **Laboratory National Patient Safety Goals subset.**

JCAHO Laboratory Patient Safety Goals

- **Improve the accuracy of patient identification**
- **Improve the effectiveness of communication among care givers**
- **Reduce the risk of health care associated infections**
- **Encourage patients' active involvement in their own care as a patient safety strategy**

College of American Pathologists

- Many checklist items added
- Plan to address Patient safety issues
- Lack of tolerance for persistent problems
- Special focus of areas previously not addressed
 - e. g. HER2/NEU

CAP

Patient Safety Goals

- **Improve patient and sample identification**
- **Improve the verification and communication of life threatening or life altering information**
- **Improve the identification, communication and correction of errors**
- **Improve coordination of laboratory patient safety role within a healthcare organization**

Error Reduction

- **Sustained error reduction generally comes with a comprehensive persistent effort**
- **Unlikely to succeed with one intervention**
- **Continuously examine and redesign systems**
- **Build in prevention and detection systems**

Error Reduction

- **Build in QA and QC monitors**
- **Continuously monitor and analyze QA and QC data**
- **Intervene at the earliest sign of variations**
- **Share quality assurance data**
- **Communicate to all workers that their work matters to patients**

Factors That Lead to Errors

- **Hand-offs**
 - **Weak links**
- **Complexity**
 - **Risk of error increases with every step**
- **Inconsistency**
 - **Level of training, performance, procedures, communication, language or taxonomy**

Factors That Lead to Errors

- **Human intervention**
 - **Machines are better at routine tasks**
 - **Humans are better in unexpected conditions**
- **Time constraints**
 - **Forces compromise**
- **Inflexible hierarchical culture**

Error Reduction in Surgical Pathology

- **Standardize all procedures**
 - **Gross room, histology, reporting**
- **Remove distractions**
 - **Accessioning, dissection, cutting, microscope**
 - **Make people aware of this potential**
- **Automate where possible**
 - **Stainers, slide and block labels**
 - **Comprehensive computer systems**

Error Reduction in Surgical Pathology

- **Remove inconsistent tools**
 - **Handwriting**
- **Reduce complexity**
 - **Automation**
 - **Lean design**
- **Make everyone aware of hand-offs (problem points)**
- **Reduce reliance on memory**
 - **Checklists**

Error Reduction in Surgical Pathology

- **Enhance communication**
 - **Electronic medical record**
- **Adequate and appropriate staffing**
 - **Batch work**
 - **Redundancy**
 - **Suitability**
- **Adequate and appropriate facilities**
 - **Space, lighting**
- **Reduce the stress level**

Where do errors happen?

- **Pre-analytic**
 - **Wrong identification: 27-38%**
 - **Defective specimens: 4-10%**
- **Analytic**
 - **Diagnostic mis-interpretation: 23-28%**
- **Post-analytic**
 - **Defective report: 28-44%**
- **Mod Pathol 18(sup):324A;2005 (abstract)**

Pre-analytic

- **CAP study of 1 million surgical specimens in 417 Laboratories**
 - **6% deficiencies (Median 3.4%)**
 - **Specimen ID problems 9.6%**
 - **Information problems 77%**
 - **Handling problems 3.6%**
 - **Others 9.7%**

Arch Pathol Lab Med 1996;120:227

Pre-analytic

- **Specimen identification**
 - **Mishaps have led to wrong surgeries**
 - **Basis for diagnostic accuracy**
 - **Multifactorial**
 - **Numerous individuals outside the lab**
 - **Requires adoption as an institutional goal**
 - **JCAHO and CAP**
 - **Cardinal patient safety goals**

Pre-analytic

- **Clinical information in surgical pathology**
- **771,475 case from 341 institutions**
- **2.4% of cases have no history**
- **5594 (0.73%) required additional information**
- **31% resulted in a delay in diagnosis**
- **6.1% of cases new information lead to substantial change in diagnosis**

Arch Pathol Lab Med 1999;123:615-619

Pre-analytic Clinical Information

- **Study of amended reports**
 - **10% additional clinical history**
 - **20% clinician identifies clinicopathologic discrepancy**
 - **Arch Pathol Lab Med. 1998;122:303-309**
- **Malpractice Claims**
 - **20% failure to obtain all relevant information**
 - **Am J Surg Pathol 1993;17:75-80**

Pre-analytic

- **Clinical history**
 - **Affects diagnostic accuracy**
 - **R/O tumor**
 - **Medical disease**
 - **Affects report completeness**
 - **No published studies on attempts to improve clinical history**

Improve Information Access

- **Electronic medical record**
 - **Easy access to clinical information,**
 - **Time saver**
 - **Clinical correlation**
 - **Ask questions**
- **History at frozen section**
 - **Focus on question at hand**



Pre-analytic

- **Solutions**
 - **Band aids don't work**
 - **Must be made an institutional goal**
 - **Sustained awareness campaign**
 - **Change the culture**
 - **Strict adherence to labeling standards**
 - **Access to electronic medical record**

Simpson JB, Clin Leadersh Manag Rev 2001;15:401-405

Analytic

- **Analytic phase**
 - **Gross exam**
 - **Dissection-sectioning**
 - **Blocks**
 - **Histology**
 - **Processing-embedding-cutting**
 - **Staining/special stain/IHC**
 - **Slide interpretation/diagnosis**
 - **Diagnostic accuracy - Measure of the effectiveness of all manipulations of the specimen**

Diagnostic accuracy

- **Peer review**
 - **No method superior in detecting errors**
 - Review of a randomly selected % of cases
 - Focused internal review of specific organ system or malignancy type (e.G. Breast cancer)
 - Interdepartmental conferences (e.G. Tumor board)
 - Intradepartmental quality assurance conference
 - Frozen section/permanent section correlation
 - Cytology/surgical pathology correlation
 - Review of previous pathology material
 - Intradepartmental review of material prior to release to other institutions
 - Review of outside diagnosis of in-house cases

Diagnostic Discrepancy

- 2003 Q-Probes data, 71 Labs
- 5255 SP cases reviewed
- 6.8% discrepancy rate
 - Margin 4%
 - Categorical 21%
 - Same Category 48%
 - Patient Information 9%
 - Typographical 18%

Arch Pathol Lab Med 2005;129:459-466

Diagnostic Discrepancy

- **Error Type**
 - **False negative** 33%
 - **False positive** 6%
 - **Grading** 2%
 - **Margins** 2%
 - **Threshold** 29%
 - **Type** 29%
 - **Clerical** 1%

- **Am J Clin Pathol 2007;127:144-152**

Errors

- **What is the best method to find errors?**

Error Detection

Method of detection	ID errors %	DX errors %	Other info errors %
Add Clinical Info	9	10	8
Clinician req.	<u>19</u>	<u>20</u>	<u>33</u>
QA Slide review	2	<u>10</u>	<u>13</u>
Consultation	3	<u>27</u>	<u>15</u>
Text review	<u>22</u>	6	9
Chance	<u>10</u>	<1	<1
Other	<u>31</u>	5	5

Errors

- **What is a reasonable error rate ?**

Error Rates

	# of Cases	Case Selection	Error Rate(%)	Significant error Rate(%)
Safrin & Bark, 1993	5,397	Consecutive	0.5	0.26
Whitehead, 1985	3,000	Consecutive	7.8	0.96
Lind, 1995	2,694	Diagnostic Bx	13	1.2
Lind, 1995	480	Random	12	1.7

Error Rates

Inter-institutional review

	Error Rate (%)	Significant Error Rate (%)
Kronz, 1999	N/A	1.4
Abt, 1995	7.8	5.8
Gupta, 2000	1—30	2—5
Malhotra, 1996	11.6	N/A
Weir, 2001	6.8	3.7

Errors

- **What is a reasonable error rate ?**

Second Opinion

- **Value of Second Opinions Is Underscored in Study of Biopsies** *By Laurie Tarkan, April 4, 2001, NY Times*
- **Misdiagnosing Cancer. Patients Should Always Consult a Second Opinion** *By John Mckenzie May 8, 2001 ABCNews*
- **Risk of Error May justify Second Opinion on Pathology Reports** *By Tara Parker-Pope Wall Street Journal April 13,2001*

Consultations

- **0.5% of all cases (median .7%, 0-2%)**
 - Arch Pathol lab med 2002;126:405-412
- **Less in larger groups**
 - **Presence of experts on staff**
- **ASCP guidelines**
 - Am J Clin Pathol 2000;114:329-335
 - **Problem prone case**
 - **Defined by the individual, group, clinician, patient or literature**

Frequency of Routine Second Opinion

Malignant diagnosis

Breast CA on needle Bx	42%
Prostate CA on needle Bx	43%
Melanoma	58%
GI CA on biopsy	34%

Unpublished data (2001) from PIP program

Frequency of Routine Second Opinion

Benign diagnosis

Benign breast biopsy	6%
Benign prostate biopsy	18%
Nevus	8%

Unpublished data (2001) from PIP program

Routine Second Opinion

- **13% of case were seen by >1 pathologist**
- **Disagreement rate 4.8% vs. 6.9%, P=.004**
- **Amended report rate 0.0 vs. 0.5%**
- **Best selection of case to be reviewed remains unknown**

Am J Clin Pathol 2006;125:737-739

Routine Second Opinion

- **Comparison of rates of misdiagnoses over two one yr periods**
 - **Without routine second review**
 - **With routine second review**
- **Results**
 - **10 misdiagnoses without review out of 7909 cases (1.3%)**
 - **5 misdiagnoses with review out of 8469 cases (0.6%)**

Pathology Case Review 2005;10:63-67

Second Opinion as a Preventative Measure

- **Prospective review (before sign out) reduces amended reports**
- **Most institutions have adopted this on specific cases (e.g. breast, prostate, pigmented skin lesions etc)**
- **Few have complete double sign-out**

Error Factors

- **Factors that correlated with error**
 - Pathologist
 - Specimen type (brst, gyn >>GI, Skin)
 - Diagnosis (nondx, atypia >>neg)
 - Dermatopathology subspecialization
 - #of pathologist on report
- **Factors not correlated with error**
 - Workload
 - Years of experience
 - Use of special stains
- **Am J Clin Pathol 2007;127:144-152**

Post-Analytic

- **Post-analytic phase**
 - **Dictation**
 - **Transcription**
 - **Report completeness**
 - **Verification**
 - **Report delivery**
 - **Critical Values**

Post-analytic

- **Complete reporting**
 - **Evidence based medicine: oncology**
 - **Commission on Cancer of the American College of Surgeons**
 - ***Cancer Program Standards 2004***
 - **90% of cancer reports must have required elements based on the CAP's publication *Reporting on Cancer Specimens***
 - **Summary checklists**

Post-analytic

- **Branston et al. European J Cancer 38;764:2002**
 - **Randomized controlled trial of computer form-based reports**
 - **16 hospitals in Wales**
 - **1044 study , 998 control**
 - **28.4% increase in report completeness**
 - **Acceptable by pathologist**
 - **Preferred by clinicians**

Post-Analytic

- **Mars and Venus**
 - Arch Pathol Lab Med 2000;124:1040
- **Clinicians misunderstood pathology reports 30% of the time**
- **Experience helped**
- **Stylistic improvements to formatting may interfere with comprehension**

Critical Diagnoses (Critical Values)

- **ADASP: establishing anatomic pathology critical diagnosis guideline represents a practice improvement and patient safety initiative.**
- **Should be customized at each institution**
- **Am J Surg Pathol 2006;30:897**

Conclusions

- **Government**
- **Accrediting agencies**
- **Factors contributing to errors**
- **Error reduction and prevention**

Conclusion

Keys to Reducing Errors

- **Fully integrated computer system**
- **Automate**
- **Integration of error prevention and detection**
- **Enhance communication**
- **Communicate to all that work matters to patients**
- **Increase awareness of problem points (hand-offs)**
- **Share quality assurance data**