Identifying and Avoiding Errors in Surgical Pathology

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ERRORS IN SURGICAL PATHOLOGY
Objectives

At the end of this presentation attendees will be able to,

• list and assess patient safety risks in their own practices

• develop strategies for reducing clinically significant diagnostic errors.
Report of the Institute of Medicine (IOM) Committee on Quality of Health Care in America
November, 1999
Institute of Medicine (IOM)

http://www.iom.edu/

Quality of Health Care in America Committee/Project, June 1998

Charge: Develop a strategy that will result in a threshold improvement in quality over the next ten years
To Err Is Human: Building a Safer Health System

The Problem?

• Betsy Lehman, health reporter for Boston Globe, died from overdose during chemotherapy
To Err Is Human: Building a Safer Health System

The Problem?

- Betsy Lehman, health reporter for *Boston Globe*, died from overdose during chemotherapy
- Willie King had the wrong leg amputated
To Err Is Human: Building a Safer Health System

The Problem?

• Betsy Lehman, health reporter for *Boston Globe*, died from overdose during chemotherapy

• Willie King had the wrong leg amputated

• Ben Kolb, an 8-year-old, died from a medication error during “minor” surgery
To Err Is Human: Building a Safer Health System

The Problem?

• 44,000 to 98,000 Americans die each year as a result of medical errors
To Err Is Human: Building a Safer Health System

The Problem?

- 44,000 to 98,000 Americans die each year as a result of medical errors

- medical errors exceed the number of deaths attributable to the 8th-leading cause of death
  
  – more than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516)
To Err Is Human: Building a Safer Health System

The Problem?

- 44,000 to 98,000 Americans die each year as a result of medical errors
- Medical errors exceed the number of death attributable to the 8th-leading cause of death
  - more than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516)

- Total national costs = $17-$29 billion annually
To Err Is Human: Building a Safer Health System

The Problem?

“The goal of this report is to break the cycle of inaction. . . .
“The goal of this report is to break the cycle of inaction. . . . Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort.”
“the surgeon called Kastrup into her office and confessed that the lymph nodes had never made it to the lab”
• “the surgeon called Kastrup into her office and confessed that the lymph nodes had never made it to the lab”

• “In 1992, Joann O’Kane, 31, of Frankfort, Illinois, scheduled her annual Pap smear. The result: negative. But nearly three years later, while pregnant with her third child, O’Kane was diagnosed with advanced cervical cancer . . . The earlier test clearly showed that O’Kane already had cervical cancer.”
"Tissue from McDougal's biopsy was switched with tissue from another woman."
Hospital errors of greater interest to American public than Richard Gere’s happiness and ground breaking news regarding sex with aging!
Reader's Digest

#1 Secret To A Sharper Brain
5 WAYS TO SPOT A LIAR
Iran Threat
What You Need To Know

NIC CAGE
The Inspiring Story He Had to Tell

PLUS
Where All That Gas Money Goes
America’s Worst Judges
Broken Family, Tender Reunion

How Doctors Gamble With Your Life
7 Ways to Protect Yourself

August 2006
$3.49
rd.com
Donor Mix-Up Leaves Girl, 17, Fighting for Life

ABSTRACT - Jessica Santillan, 17, is in critical condition on life support at Duke University Hospital after mistakenly being given heart and lung transplant from donor with incompatible bloodtype; her body rejected organs and doctors see little chance of survival without another transplant, which is unlikely given shortage of organs; Duke accepts responsibility for tragic error in giving organs from donor with Type A blood to Santillan, who has Type O; will now require additional checking of blood types; Santillan family moved from Mexico three years ago in hopes of treatment for girl's cardiomyopathy.

by Denise Grady
PERSONAL EXPERIENCES WITH MEDICAL ERRORS

![Bar chart showing personal experiences with medical errors.

- 35% of MDs (n=831) reported errors in their own or family member's care.
- 42% of the public (n=1207) reported errors in their own or family member's care.

Errors in own or family member's care: 0%, 10%, 20%, 30%, 40%, 50%.

MDs (n=831), Public (n=1207).]
PERSONAL EXPERIENCES WITH MEDICAL ERRORS

Errors in own or family member's care
- MDs (n=831): 35%
- Public (n=1207): 42%

Serious health consequences
- MDs (n=831): 18%
- Public (n=1207): 24%

Death
- MDs (n=831): 7%
- Public (n=1207): 10%
ERRORS IN SURGICAL PATHOLOGY
Conclusions

• the public is on to us and they’re not going to take it anymore
ERRORS IN SURGICAL PATHOLOGY
Conclusions

• the public is on to us and they’re not going to take it anymore

• significant errors occur in anatomic pathology practice at a low but predictable frequency
“Research at Johns Hopkins University in Baltimore has shown that about 1.4% of pathology cases involve serious errors . . . It's difficult to estimate an exact figure, but it's believed that several thousand patients each year are seriously misdiagnosed.”
Error Rates in Surgical Pathology
Detection Methods

• secondary review/audit
  – retrospective vs prospective
  – consecutive vs selected cases
Error Rates in Surgical Pathology
Prospective Peer Review

- Total errors:
  - Safrin and Bark: 0.26%
  - Whitehead et al: 2.20%
  - Lind et al.: 14.10%

- Significant errors:
  - Safrin and Bark: 0.96%
  - Whitehead et al: 0.96%
  - Lind et al.: 1.20%
Secondary review identified 415 (6.7%) “discrepancies” in 6,186* specimens from 74 institutions.

* 5,268 surg path
847 cytol

Error Rates in Anatomic Pathology
Measuring Discrepancy Frequencies and Causes*

Discrepancies were detected with greater frequency in patients reviewed at clinician request ($P < .001$)

![Bar chart showing error rates.]

Reason for case review correlates with patient “outcome” \( (P = .02) \)

disagreement = any change in diagnosis that might be clinically significant
Error Rates in Surgical Pathology

- Patient and/or clinician generated (18)
  - No. of Errors: 2
  - No. with follow-up: 6

- Pathologist generated (55)
  - No. of Errors: 8
  - No. with follow-up: 14

- Incoming (35)
  - No. of Errors: 15
  - No. with follow-up: 19
Patient Safety and Pathology

“. . . diagnostic disagreement is not the same as error.”

Error Rates in Surgical Pathology
Detection Methods

• secondary review/audit
  – retrospective vs prospective
  – consecutive vs selected cases

• amended report rates
Error Rates in Surgical Pathology
Types of Errors Reflected in Amended Reports

- 3,147 (0.19%) amended reports in 1,667,547 cases

0.0% 10.0% 20.0% 30.0% 40.0%
Final diagnosis: 38.7%
Patient ID: 19.2%
Prelim Dx: 15.6%
Other clin info: 26.5%

Error Rates in Surgical Pathology
Detection Methods

• secondary review/audit
  – retrospective vs prospective
  – consecutive vs selected cases

• amended report rates

• prospective surveys (Q Probes)
Error Rates in Surgical Pathology
Specimen Identification and Accessioning

• 6% of cases

• types of deficiencies
  – specimen identification 9.6%
  – inaccurate information 77.0%
  – specimen handling problems 3.6%
  – other 9.7%

“There will be greater emphasis on process design and the development of error-resistant protocols, so as to make the whole system less susceptible to ‘human’ errors. Information systems will be instrumental to most such processes and in many cases will drive these processes.”

ERRORS IN SURGICAL PATHOLOGY

Conclusions

• the public is on to us and they’re not going to take it anymore

• significant errors occur in anatomic pathology practice at a low but predictable frequency

“Information systems [are] instrumental to most such processes . . .”

Sinard & Morrow, 2001
How safe is your practice?
Types of Error

*active* errors — occur at the level of the frontline operator
Institute of Medicine (IOM)
Quality of Health Care in America Committee

Types of Error

active errors — occur at the level of the frontline operator

latent errors — tend to be removed from the direct control of the operator (e.g. poor design, poorly structured organizations, etc.)
Quality is a system property
• *Quality* is a system property

• *Every system* is perfectly designed to achieve exactly the results it gets
# Errors in Surgical Pathology

*Troxel Am J Surg Pathol 2004*

<table>
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<tbody>
<tr>
<td>“operational errors”</td>
<td>4 (1.8%)</td>
<td>22 (8%)</td>
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<tr>
<td>specimen/patient</td>
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<td>3</td>
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<tr>
<td>“floaters”</td>
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<td>3</td>
</tr>
<tr>
<td>mislabeled biopsy</td>
<td></td>
<td>3</td>
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<td>site, transcription</td>
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<tr>
<td>error</td>
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*data based on pathology claims reported to The Doctors Company, physician-owned professional liability insurance company (Napa, CA)*
Hospitals Move to Cut Dangerous Lab Errors

Improved Specimen Collection And Efficiency Help Increase Accuracy of Medical Testing

For patients, some of the most devastating medical mistakes can start in the lab, where studies show that 3% to 5% of the billions of specimens taken each year are defective, be it a biopsy that doesn't extract the tumor cells, blood that isn't drawn correctly or a mix-up with another patient's sample.
Identification Errors Involving Clinical Laboratories
Identification Errors Involving Clinical Laboratories

- 120 institutions, ~5 week study period
- identification errors detected pre- and post-verification
- adverse events (i.e. patient harm)
Identification Errors Involving Clinical Laboratories

6,705 identification errors

- 345 (1 in 18 ID errors)
  - Adverse Event

- 974 (14.5%)
  - Identified After Reporting
    - 5,731 (85.5%)
      - Identified Before Reporting
        - 324/million billable tests
reasons for identification error (n = 4,852)

- specimen label 2,691 (55.5%)
- initial registration/order entry 1,088 (22.4%)
- other clerical 604 (12.4%)
- other 205 (4.2%)
- aliquot/block/slide label 184 (3.8%)
- result entry 80 (1.7%)
# Errors in Surgical Pathology
Troxel Am J Surg Pathol 2004*

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<tr>
<td>“floaters”</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>mislabeled biopsy site,</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>transcription error</td>
<td></td>
<td></td>
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</table>

*data based on pathology claims reported to The Doctors Company, physician-owned professional liability insurance company (Napa, CA)
“... the sample her diagnosis was based on had been contaminated with cancerous cells from another patient’s specimen”
Patient Safety and Pathology
Extraneous Tissues (“floaters”)

*Gephardt & Zarbo. Arch Pathol Lab Med 1996*
ERRORS IN SURGICAL PATHOLOGY

Conclusions

- the public is on to us and they’re not going to take it anymore
- significant errors occur in anatomic pathology practice at a low but predictable frequency
- our complex processes set us up to fail
Every system is perfectly designed to achieve exactly the results it gets.

Don Berwick’s “Central Law of Improvement”
At the end of this presentation attendees will be able to,

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Designing for Safety in Health Care
IOM Committee on Quality of Health Care in America

• Provide leadership
• Respect human limits in process design
Respect Human Limits in Process Design

✓ avoid reliance on memory
✓ use constraints and forcing functions
✓ avoid reliance on vigilance
✓ simplify key processes
✓ standardize work processes
• monitor identification errors
• ensure new (i.e. “new” to LIS) patients are properly identified
• use multiple identifiers (> 2)
• match requisitions to tests ordered in the computer prior to verification
Effectiveness of Toyota Process Redesign in Reducing Thyroid Gland Fine-Needle Aspiration Error

Stephen S. Raab, MD,1 Dana Marie Grzybicki, MD, PhD,1 Daniel Sudilovsky, MD,1 Ronald Balassanian, MD,1 Janine E. Janosky, PhD,2 and Colleen M. Vrbin1

Key Words: Patient safety; Error reduction; Thyroid gland; Fine-needle aspiration; Immediate interpretation

DOI: 10.1309/N5Q1L7KATKVK9O

• standardized diagnostic terminology

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<th></th>
<th>pre-</th>
<th>post-</th>
<th>p value</th>
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<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>70.2</td>
<td>90.6</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>67.0</td>
<td>55.1</td>
<td>.082</td>
</tr>
<tr>
<td>False-negative rate (%)</td>
<td>41.8</td>
<td>19.1</td>
<td>.006</td>
</tr>
<tr>
<td>False-positive rate (%)</td>
<td>22.6</td>
<td>26.3</td>
<td>.480</td>
</tr>
<tr>
<td>Discrepancy rate (%)</td>
<td>31.0</td>
<td>24.2</td>
<td>.125</td>
</tr>
</tbody>
</table>
• Provide leadership
• Respect human limits in process design
• Promote effective team functioning
Medical Errors – “Very Important” Causes  

<table>
<thead>
<tr>
<th>Cause</th>
<th>MDs</th>
<th>Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>insufficient time spent with patients</td>
<td>37%</td>
<td>72%</td>
</tr>
<tr>
<td>overwork, stress, fatigue</td>
<td>50%</td>
<td>70%</td>
</tr>
<tr>
<td><strong>failure to work together or communicate as team</strong></td>
<td>39%</td>
<td>67%</td>
</tr>
<tr>
<td>understaffing of nurses</td>
<td>53%</td>
<td>65%</td>
</tr>
<tr>
<td>complexity of care</td>
<td>38%</td>
<td>62%</td>
</tr>
</tbody>
</table>
“In Jessica’s case, the cause of death was the single most common error cited in high-risk professions from aviation to medicine: *the failure to share key pieces of communication.*”
“This is what Carolyn Clancy, the new director of the Agency for Healthcare Research and Quality . . . thinks of every morning when she gets her coffee. ‘It occurs to me that there’s more double checking and systematic avoidance of mistakes at Starbucks than at most health care institutions.’”
• Provide leadership
• Respect human limits in process design
• Promote effective team functioning
• Anticipate the unexpected
High reliability organizations*

- The most important distinguishing feature of high reliability organizations is their collective **preoccupation with the possibility of failure.**
- They expect to make errors and train their workforce to recognize and recover them.
- They continually rehearse familiar scenarios of failure and strive hard to imagine novel ones.
Error Rates in Surgical Pathology
Analysis of 1,004,115 Cases from 417 Labs*

• deficiencies in 60,042 (6.0%) of cases
• *no action taken* for 66.3% of cases
• 64.5% (of 417) of laboratories had a written plan
  — median percentile deficiencies
    labs with plan 3.2%
    labs without a plan 8.8%

JC National Patient Safety Goals, 2006
Improve effectiveness of communication

Requirement: All values defined as critical by the laboratory are reported to a responsible licensed caregiver within time frames established by the laboratory (defined in cooperation with nursing and medical staff). When the patient’s responsible licensed caregiver is not available within the time frames, there is a mechanism to report the critical information to an alternative responsible caregiver.

Applies to: Lab
Is there a policy regarding the timely communication, and documentation thereof, of significant or unexpected surgical pathology findings?

NOTE: Certain surgical pathology diagnoses may be considered particularly significant or unexpected. Such diagnoses may include: malignancy in an uncommon location or specimen type (e.g., hernia sac, intervertebral disk material, tonsil, etc.), absence of chorionic villi when clinically expected (potential ectopic pregnancy), change of a frozen section diagnosis after review of permanent sections, and/or mycobacterial, fungal or other significant infectious organisms identified on special stains. Diagnoses to be defined as “significant” or “unexpected,” if any, should be determined by the pathology department, in cooperation with local clinical medical staff. Consideration should be given to assuring, with reasonable effort, prompt communication of such results, by telephone, pager, or other system. There should be documentation of date and time of such special notification (which may be included in the pathology report or in laboratory files).

- unanticipated diagnosis of malignancy (or vice versa)
- unexpected absence of chorionic villi
- significant change in frozen section diagnosis
- discovery of clinically significant infections
## Median for Excellent/Good Ratings for Each Service Category

<table>
<thead>
<tr>
<th>Service Category</th>
<th>Median</th>
</tr>
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<tbody>
<tr>
<td>Quality of professional interaction</td>
<td>96.3</td>
</tr>
<tr>
<td>Diagnostic accuracy</td>
<td>96.1</td>
</tr>
<tr>
<td>Pathologist responsiveness to problems</td>
<td>93.6</td>
</tr>
<tr>
<td>Pathologists’ accessibility for frozen section</td>
<td>93.3</td>
</tr>
<tr>
<td>Tumor board presentations</td>
<td>93.1</td>
</tr>
<tr>
<td>Courtesy of secretarial and technical staff</td>
<td>93.0</td>
</tr>
<tr>
<td>Communication of relevant information</td>
<td>88.5</td>
</tr>
<tr>
<td>Teaching conferences and courses</td>
<td>88.2</td>
</tr>
<tr>
<td>Notification of significant abnormal results</td>
<td>86.3</td>
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<tr>
<td>Timeliness of reporting</td>
<td>79.8</td>
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</tbody>
</table>
ANATOMIC PATHOLOGY
U. Mich Critical Values Alerts Policy and Process

critical alert values defined

definitions/policy endorsed by ECCA

critical alert values urgently communicated

report reconciled against EMR

closing the loop on communication of critical values

daily report to service director

daily report to signing faculty

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ANATOMIC PATHOLOGY
U. Mich Critical Values Alerts Policy and Process

**closing the loop on**
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daily report to service director
Patient with COPD and new lung nodule but no diagnosis. Normal bronchoscopy. Scheduled for PET in 3 weeks and follow-up visit for COPD in 3 months. Clinician notified - PET canceled
• Provide leadership
• Respect human limits in process design
• Promote effective team functioning
• Anticipate the unexpected
• Create a learning environment
Create a Learning Environment

✓ encourage reporting of errors and hazardous conditions

✓ ensure no reprisals for reporting of errors

✓ develop a working culture in which communication flows freely regardless of authority gradient

✓ implement mechanisms of feedback and learning from error
Every system is perfectly designed to achieve exactly the results it gets.

*Don Berwick’s “Central Law of Improvement”*
PATIENT SAFETY/ERROR REDUCTION
Roadblocks to Execution*

- workforce is blind to the enemy (i.e. patient injury)
- lack of scientific investigation of system failures
- improving safety costs money in the short term
- the problem of safety is a hard one

PATIENT SAFETY/ERROR REDUCTION
Three Essential Preconditions for Improvement*

• will

PATIENT SAFETY/ERROR REDUCTION
Three Essential Preconditions for Improvement*

• will
• ideas

PATIENT SAFETY/ERROR REDUCTION
Three Essential Preconditions for Improvement*

• will
• ideas
• execution

Patient safety was the tip of the iceberg . . .

William Richardson, Chair
Patient safety was the tip of the iceberg . . .

This is the rest of the iceberg.”

William Richardson, Chair
“Between the health care we have and the care we could have lies not just a gap, but a chasm. . . . As the patient safety report was a call for action to make care safer, this report is a call for action to improve the American health care delivery system as a whole, in all its quality dimensions, for all Americans.”
Six Specific Aims for Improvement

Health care should be:

• Safe
• Effective (*i.e.* avoiding underuse and overuse)
• Patient-centered
• Timely
• Efficient (*i.e.* avoiding waste)
• Equitable
“If we want safer, higher-quality care, we will need to have redesigned systems of care, including the use of information technology to support clinical and administrative processes.”
PATIENT SAFETY/ERROR REDUCTION
Three Essential Preconditions for Improvement*

• will
• ideas
• execution

Innovation

Redesign the status quo to create and deliver new value.
ERRORS IN SURGICAL PATHOLOGY
Conclusions

• we can do better!
Conclusions

- our complex processes set us up to fail
- we can do better!
ERRORS IN SURGICAL PATHOLOGY
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ERRORS IN SURGICAL PATHOLOGY

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