Safety and Quality in Anatomic Pathology

Implementing Data-Driven Feedback and Learning Mechanisms in Surgical Pathology

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Safety, Quality, & Data-Driven Learning In Surgical Pathology

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

• understand the problem of safety and quality in surgical pathology
• understand the value of systems-based thinking in addressing challenges in safety & quality
• identify specific solutions to common problems in surgical pathology quality and safety
To Err is Human
Building a Safer Health System

November, 1999
“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.”
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
• **44,000 to 98,000** Americans die each year as a result of medical errors
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• 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)
• 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
... but is surgical pathology a problem?
“the surgeon called Kastrup into her office and confessed that the lymph nodes had never made it to the lab”
“A week after the surgery, when Kara and her family returned to the hospital to receive the biopsy results, the hospital told them that because they lost the sample, no biopsy could be performed and no determination could be made as to whether or not it was cancerous.”
“... the sample her diagnosis was based on had been contaminated with cancerous cells from another patient’s specimen”
Tissue from McDougal's biopsy was switched with tissue from another woman.
U-M lab cancer mistake verdict upheld

Samples mislabeled; woman did not have breast cancer

**By Amy Whitesall**
News Staff Reporter

In 2003, a laboratory mix-up at the University of Michigan Hospitals caused Theresa Karwoski’s doctor to incorrectly diagnose her with breast cancer.

Karwoski went through a partial mastectomy, removal of seven lymph nodes, drugs and testing to fight a cancer she didn’t have.

In February, a jury awarded the 51-year-old Ann Arbor woman and her husband more than $3 million in damages in a lawsuit filed against the medical center. The verdict was upheld in the court of claims by Washtenaw Circuit Judge Timothy P. Connors, who late last month ordered U-M to pay the Karwoskis’ attorney’s fees and interest.

“$3 million in damages . . . attorney’s fees and interest.”

The next month, Dr. Alfred Chang, U-M surgical oncology chief, removed seven lymph nodes and took tissue from the breast and the area around the lymph nodes, Garris said. When the pathology report on the tissue that was removed failed to show any cancer, Karwoski went through nuclear medicine and radiological tests to look for the cancer.

Karwoski pushed for answers, and in July 2003 UMHS cytopathology director Dr. Claire Michael discovered the labeling mistake, Garris said.

Today, because of the surgery, Karwoski has a permanent condition called lymphedema, a swelling of her left arm and chest that requires physical therapy and periodic draining of fluid, Garris said.

The attorney said Karwoski ended up losing her job and sued U-M for both malpractice and negligence, he said.

“(Karwoski) didn’t want go through a trial,” Garris said. “That was very traumatic to her, but she felt the jury paid great attention throughout the trial and made a just decision.”

ask questions,” Garris said.

Although it does not contest the misdiagnosis occurred, the university will appeal the verdict as inappropriate based on the evidence at trial, UMHS spokeswoman Kallie Michels said Monday. The health system has since added extra labeling in the five-point process it uses to make sure samples are assigned to the right patient.

"From the start we acknowledged our error to Ms. Karwoski and apologized sincerely for it,” Michels said. “This error has never occurred before, and we took extraordinary measures to ensure it never would again.”

In April 2003, Karwoski went through a procedure to have fluid and cells drawn from her left breast and submitted for testing because of a thickening in that breast. But, according to Garris, the lab clerk processing the sample put the wrong number on the slide, and Karwoski’s sample was mixed up with that of a male patient who did have cancer. It is unclear what happened to that patient.
When she heard the diagnosis of invasive lobular carcinoma, Darrie Eason had but one thought: Please don't let me die.

Four months and a double mastectomy later, doctors told Eason that her tissue sample had been mislabeled, and that she never had cancer.

“I didn’t know what to believe,” said Eason, a 35-year-old single mother from Long Beach. “They told me I had cancer and now they’re telling me I didn’t. I didn’t know if the next day they were going to call me and say, ‘Sorry, we made a mistake, you really do have cancer.’”

According to her lawyer, York State health officials are investigating how Eason is the victim of a rare mix-up in a tissue case. Eason is a resident of Brook, N.Y. Eason, who filed a medical malpractice lawsuit against CBLPath in State Supreme Court in Mineola last month seeking an undisclosed sum of money.

The 11 1/2-page state report, issued last August to CBLPath, refers to a company report that blamed the mix-up on a technician who admitted cutting corners while labeling tissue specimens.

CBLPath chief executive William Curtis said he was familiar with Eason’s case but could not speak about any of his company’s patients because of federal privacy laws. He
...and safety is not the only problem!
Report: Health system broken

USA TODAY, March 2-4, 2001

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.”
Crossing the Quality Chasm: A New Health System for the 21st Century

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.”
At the end of this lecture attendees will be able to,

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Types of Error

**active** errors — occur at the level of the frontline operator

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

The "blunt end" of complex health care system

Every system is perfectly designed to achieve exactly the results it gets.

Don Berwick’s “Central Law of Improvement”
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pre-analytical phase errors
Error Rates in Surgical Pathology
Specimen Identification and Accessioning Defects*

1993
417 participants (393 USA)
surgical tissue cases
4,000 sequential accessions
all cases received in 4 months
400 deficiencies

Error Rates in Surgical Pathology
Specimen Identification and Accessioning Defects*

- Specimen ID: 10%
- Other: 10%
- Specimen handling: 4%
- 60,042 (6.0%) deficiencies
- 77% incomplete/missing information

Error Rates in Surgical Pathology

Specimen Information Defects*

52,607 specimen information defects

Error Rates in Surgical Pathology
Specimen Identification Defects*

Identification Errors Involving Clinical Laboratories

6,705 identification errors
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%)
Error Rates in Surgical Pathology
Surgical Specimen Identification Errors*

- prospective cohort study (Johns Hopkins)
- outpatient clinic + hospital ORs
- all patients for whom surgical specimen was sent to pathology (OCT04-APR05)
- \textbf{ID error} = specimen requisition and specimen label mismatch

*from Makary et al. Surgery 2007; 141: 450-5.*
### Error Rates in Surgical Pathology

**Surgical Specimen Identification Errors***

91/21,351 specimens with ID error (rate = 4.3/1,000)

<table>
<thead>
<tr>
<th>Events</th>
<th>% of specimens</th>
<th>Rate (per 1,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR specimens (10,354)</td>
<td>38</td>
<td>0.4%</td>
</tr>
<tr>
<td>Clinic specimens (10,997)</td>
<td>53</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

*from Makary et al. Surgery 2007; 141: 450-5.*
Error Rates in Surgical Pathology

Surgical Specimen Identification Errors*

*from Makary et al. Surgery 2007; 141: 450-5.
## Error Rates in Surgical Pathology

### Surgical Specimen Identification Errors*

<table>
<thead>
<tr>
<th>Error type</th>
<th>Clinic</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events (%)</td>
<td>Rate (/1000)</td>
</tr>
<tr>
<td>Not labeled</td>
<td>6 (11.3)</td>
<td>0.55</td>
</tr>
<tr>
<td>Empty container</td>
<td>11 (20.8)</td>
<td>1.00</td>
</tr>
<tr>
<td>Incorrect laterality</td>
<td>11 (20.8)</td>
<td>1.00</td>
</tr>
<tr>
<td>Incorrect site</td>
<td>9 (17.0)</td>
<td>0.82</td>
</tr>
<tr>
<td>Incorrect patient</td>
<td>7 (13.2)</td>
<td>0.64</td>
</tr>
<tr>
<td>No patient name</td>
<td>3 (5.7)</td>
<td>0.27</td>
</tr>
<tr>
<td>No tissue site</td>
<td>6 (11.3)</td>
<td>0.55</td>
</tr>
</tbody>
</table>

*from Makary et al. Surgery 2007; 141: 450-5.*
## Error Rates in Surgical Pathology

### Surgical Specimen Identification Errors*

<table>
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<td>0.55</td>
</tr>
<tr>
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<td>1.00</td>
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<tr>
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<td>9 (17.0)</td>
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<tr>
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<td>0.27</td>
</tr>
<tr>
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## Error Rates in Surgical Pathology

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<th>Error type</th>
<th>Clinic Events (%)</th>
<th>Clinic Rate (/1000)</th>
<th>OR * Events (%)</th>
<th>OR * Rate (/1000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not labeled</td>
<td>6 (11.3)</td>
<td>0.55</td>
<td>12 (31.6)</td>
<td>1.16</td>
</tr>
<tr>
<td>Empty container</td>
<td>11 (20.8)</td>
<td>1.00</td>
<td>5 (13.2)</td>
<td>0.48</td>
</tr>
<tr>
<td>Incorrect laterality</td>
<td>11 (20.8)</td>
<td>1.00</td>
<td>5 (13.2)</td>
<td>0.48</td>
</tr>
<tr>
<td>Incorrect site</td>
<td>9 (17.0)</td>
<td>0.82</td>
<td>5 (13.2)</td>
<td>0.48</td>
</tr>
<tr>
<td>Incorrect patient</td>
<td>7 (13.2)</td>
<td>0.64</td>
<td>4 (10.5)</td>
<td>0.38</td>
</tr>
<tr>
<td>No patient name</td>
<td>3 (5.7)</td>
<td>0.27</td>
<td>6 (15.8)</td>
<td>0.58</td>
</tr>
<tr>
<td>No tissue site</td>
<td>6 (11.3)</td>
<td>0.55</td>
<td>1 (2.6)</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*from Makary et al. Surgery 2007; 141: 450-5.*
### Designing for Safety in Surgical Pathology

#### Countermeasures for Pre-Analytical Errors

<table>
<thead>
<tr>
<th>Associated with lower rates of defects</th>
<th>Associated with higher rates of defects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>lower numbers (&lt;15,000) of accessioned cases</strong></td>
<td><strong>specimen &amp; requisition in unique second container</strong></td>
</tr>
<tr>
<td><strong>formal plan for error detection</strong> in specimen identification and accessioning</td>
<td><strong>specimen container labeled with only 1 identifier</strong></td>
</tr>
</tbody>
</table>

Designing for Safety in Surgical Pathology
Countermeasures for Pre-Analytical Errors

The Henry Ford Production System
Measures of Process Defects and Waste in Surgical Pathology as a Basis for Quality Improvement Initiatives


Visual data display poster showing data entries by pathologists that captured detail on misidentifications arising in the surgical pathology process.
Michigan Pathology Quality System
Quality – Safety – Efficiency – Service – Satisfaction

Just-in-Time
- Pacing by Demand
- Continuous Flow
- Pull Systems

Built-in-Quality
- Error Proof
- Surface Problems
- Stop and Respond to Abnormalities
- Solve Problems at Root Cause

Customer Defines Value

Leveled Workload

Continuous Improvement (P-D-C-A) and Learning
- Robust Processes
- Organized Workplace (5S)
- Visual Control

Standardized Work
- Reliable, Tested
- Serve People and Processes
- Preventive Maintenance - TPM

Make Value Flow By Eliminating Errors and Waste

MQS Methods (All Mission) Sources: J. Shook, J. Billi, J. Liker, S. Hoeft, Park-Nicollet /jmk 04.09..07
Designing for Safety in Surgical Pathology
Countermeasures for Pre-Analytical Errors

Provider order entry

"... 25 percent reduction in result reporting time ($p=0.001$)."

Designing for Safety in Surgical Pathology
Countermeasures for Pre-Analytical Errors

computer-assisted bar-coding/RFID

Figure 2. Frequency of mislabeled specimens, September 2003 to August 2006.

Designing for Safety in Surgical Pathology
Countermeasures for Pre-Analytical Errors

computer-assisted bar-coding/RFID

Table. Accessions and labeling errors before, during, and after intervention

<table>
<thead>
<tr>
<th>Factor</th>
<th>Period</th>
<th>Mean percent</th>
<th>SD</th>
<th>Median percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mislabeled samples</td>
<td>Sep 2003-Aug 2004</td>
<td>0.032</td>
<td>0.012</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>Sep 2004-Aug 2005</td>
<td>0.015</td>
<td>0.011</td>
<td>0.012</td>
</tr>
<tr>
<td></td>
<td>Sep 2005-Aug 2006</td>
<td>0.005</td>
<td>0.008</td>
<td>0</td>
</tr>
<tr>
<td>Unlabeled samples</td>
<td>Sep 2003-Aug 2004</td>
<td>0.065</td>
<td>0.017</td>
<td>0.066</td>
</tr>
<tr>
<td></td>
<td>Sep 2004-Aug 2005</td>
<td>0.08</td>
<td>0.029</td>
<td>0.074</td>
</tr>
<tr>
<td></td>
<td>Sep 2005-Aug 2006</td>
<td>0.068</td>
<td>0.026</td>
<td>0.073</td>
</tr>
<tr>
<td>Accessions per month</td>
<td>Sep 2003-Aug 2004</td>
<td>17,247</td>
<td>1846.4</td>
<td>18,803</td>
</tr>
<tr>
<td></td>
<td>Sep 2004-Aug 2005</td>
<td>17,566</td>
<td>1517.6</td>
<td>17,152</td>
</tr>
<tr>
<td></td>
<td>Sep 2005-Aug 2006</td>
<td>17,793</td>
<td>1233.2</td>
<td>17,542</td>
</tr>
</tbody>
</table>

Designing for Safety in Surgical Pathology
Countermeasures for Pre-Analytical Errors
computer-assisted bar-coding/RFID
Designing for Safety in Surgical Pathology

Countermeasures for Pre-Analytical Errors

AP middleware for label/cassette printing
Designing for Safety in Surgical Pathology

Countermeasures for Pre-Analytical Errors

- formal written plan for error detection and problem resolution
- application of Lean principles and tools
- provider order entry
- electronic positive patient identification
- software solutions that maintain fidelity of patient ID across key handoffs
analytical phase errors

surgical pathology is a team activity!
### Errors in Surgical Pathology

**Troxel Am J Surg Pathol 2004**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“operational errors”</td>
<td>4 (1.8%)</td>
<td>22 (8%)</td>
</tr>
<tr>
<td>specimen/patient misidentification</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>lost specimens</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>“floaters”</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>mislabeled biopsy site, transcription error</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

*data based on pathology claims reported to The Doctors Company, physician-owned professional liability insurance company (Napa, CA)
Extraneous Tissues ("floaters")

*Gephardt & Zarbo. Arch Pathol Lab Med 1996*
Medical Errors – “Very Important” Causes

- insufficient time spent with patients
  - MDs: 37%
  - Public: 72%
- overwork, stress, fatigue
  - MDs: 50%
  - Public: 70%
- failure to work together or communicate as team
  - MDs: 39%
  - Public: 67%
- understaffing of nurses
  - MDs: 53%
  - Public: 65%
- complexity of care
  - MDs: 38%
  - Public: 62%
Designing for Safety in Health Care


Patient Safety Culture Composites

<table>
<thead>
<tr>
<th></th>
<th>Average % Positive Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Teamwork Within Units</td>
<td>79%</td>
</tr>
<tr>
<td>2. Supervisor/Manager Expectations &amp; Actions Promoting Patient Safety</td>
<td>75%</td>
</tr>
<tr>
<td>3. Management Support for Patient Safety</td>
<td></td>
</tr>
<tr>
<td>4. Organizational Learning–Continuous Improvement</td>
<td></td>
</tr>
<tr>
<td>5. Overall Perceptions of Patient Safety</td>
<td></td>
</tr>
<tr>
<td>6. Feedback &amp; Communication About Error</td>
<td></td>
</tr>
<tr>
<td>7. Communication Openness</td>
<td></td>
</tr>
<tr>
<td>8. Frequency of Events Reported</td>
<td></td>
</tr>
<tr>
<td>9. Teamwork Across Units</td>
<td></td>
</tr>
</tbody>
</table>

web-based service team calendars
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
“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.’”
Staff are afraid to ask questions when something does not seem right.

Staff feel free to question the decisions or actions of those with more authority.

Staff will freely speak up if they see something that may negatively affect patient care.
Staff feel like their mistakes are held against them.

When an event is reported, it feels like the person is being written up, not the problem.

Staff worry that mistakes they make are kept in their personnel file.
Error Rates in Surgical Pathology
Amended Reports as a Measure of Diagnostic Error*

Amended Report Frequency (per 1,000 cases) by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Report Defect</th>
<th>Misidentification</th>
<th>Misinterpretation</th>
<th>Specimen Defect</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>2.8</td>
<td>263</td>
<td>68%</td>
<td>100%</td>
</tr>
<tr>
<td>2002</td>
<td>2.6</td>
<td>196</td>
<td>39%</td>
<td>92%</td>
</tr>
<tr>
<td>2003</td>
<td>3.4</td>
<td>168</td>
<td>25%</td>
<td>75%</td>
</tr>
<tr>
<td>2004</td>
<td>4.8</td>
<td>51</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*from Meier et al. Am J Clin Pathol 2008; 130: 238-46
Error Rates in Surgical Pathology
Diagnostic Disagreement as a Measure of Error

Prospective/Blinded Re-Review
(Significant errors – 0.3%-1.2%)

Whitehead et al 1984: 1.0%
Safrin and Bark 1993: 0.3%
Lind et al. 1995: 1.2%
Weydert et al 2005: 0.3%
Renshaw and Gould 2006: 0.8%
Error Rates in Surgical Pathology
Diagnostic Disagreement as a Measure of Error

Interinstitutional Re-Review (“consults”)
(Significant errors – 1.4%-5.8%)

- Abt et al 1995: 5.8%
- Kronz et al 1999: 1.4%
- Weir et al 2003: 3.7%
- Tsung 2004: 3.8%
Error Rates in Surgical Pathology

Diagnostic Disagreement as a Measure of Error

Retrospective Re-Review
(Significant errors – 0.4%-3.2%)

-focused subspecialty based review

5% random review

Total disagreements
Significant errors

Whitehead et al 1986
Ramsay et al 1992
Raab et al 2005
Raab et al 2008
Raab et al 2008
Error Rates in Surgical Pathology
Measuring Frequency of Diagnostic Discordance

Renshaw & Gould.
Am J Clin Pathol 2005

Raab et al.
Arch Pathol Lab Med 2005
Error Rates in Anatomic Pathology

![Bar chart showing error rates in anatomic pathology]

- **Patient and/or clinician generated (18):**
  - No. of Errors: 2
  - No. with follow-up: 6
  - Error Rate: 33%

- **Pathologist generated (55):**
  - No. of Errors: 8
  - No. with follow-up: 14
  - Error Rate: 57%

- **Incoming (35):**
  - No. of Errors: 15
  - No. with follow-up: 19
  - Error Rate: 79%
“. . . diagnostic disagreement is not the same as error.”

Gorillas in our midst: sustained inattentional blindness for dynamic events

Daniel J Simons, Christopher F Chabris
Department of Psychology, Harvard University, 33 Kirkland Street, Cambridge, MA 02138, USA; e-mail: dsimons@wjh.harvard.edu
Received 9 May 1999, in revised form 20 June 1999

half of observers fail to notice an ongoing, highly salient but unexpected event while engaged in a primary monitoring task

observers are more likely to notice unexpected events if these events are visually similar to the events to which they are attending

objects can pass through the spatial extent of attentional focus and still not be ‘seen’ if they are not specifically being attended
Blind Drunk: The Effects of Alcohol on Inattentional Blindness

SEEMA L. CLIFASEFI1*, MELANIE K. T. TAKARANGI2 and JONAH S. BERGMAN1

1University of Washington, USA
2Victoria University of Wellington, New Zealand

Table 1. Percentage of subjects who noticed the gorilla by condition

<table>
<thead>
<tr>
<th></th>
<th>Got alcohol (%)</th>
<th>Got tonic (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Told alcohol</td>
<td>18</td>
<td>42</td>
</tr>
<tr>
<td>Told tonic</td>
<td>18</td>
<td>50</td>
</tr>
</tbody>
</table>
Designing for Safety in Surgical Pathology
Countermeasures for Analytical Errors

Anticipate the predictable
Designing for Safety in Surgical Pathology
Countermeasures for Analytical Errors

Anticipate the predictable

Designing for Safety in Surgical Pathology
Countermeasures for Analytical Errors

Measure real-time diagnostic trends*

*data idealized and not drawn from actual cases or pathologists
Designing for Safety in Surgical Pathology

Countermeasures for Analytical Errors

• formal written plan for error detection and problem resolution
• application of Lean principles and tools
• electronic positive patient identification at multiple fiduciary tracking points
• aspire to a culture of safety
  communication across authority gradients
  error reporting
Designing for Safety in Surgical Pathology

Countermeasures for Analytical Errors

- forced functions predicated on specific QA initiatives (selected prospective re-review)
- real-time monitoring of diagnostic trends
- delivery of “just-in-time” case specific content
- commitment to service
Just-in-Time

- Pacing by Demand
- Continuous Flow
- Pull Systems

Built-in-Quality

- Error Proof
- Surface Problems
- Stop and Respond to Abnormalities
- Solve Problems at Root Cause

Michigan Pathology Quality System

Quality – Safety – Efficiency – Service – Satisfaction

Leveled Workload

- Work Force
  - Skilled, Capable, Flexible
  - Engaged, Motivated
  - Design Work, Solve Problems

Continuous Improvement (P-D-C-A) and Learning

- Methods
  - Robust Processes
  - Organized Workplace (5S)
  - Visual Control

- Technology and Equipment
  - Reliable, Tested
  - Serve People and Processes
  - Preventive Maintenance - TPM

Standardized Work

- Materials
  - Materials Readiness
  - Supplier involvement

Customer Defines Value

Make Value Flow By Eliminating Errors and Waste

MQS Methods (All Mission) Sources: J. Shook, J. Billi, J. Liker, S. Hoeft, Park-Nicollet /jmk 04.09..07
Customer Satisfaction in AP

Median for Excellent/Good Ratings for Each Service Category

- Quality of professional interaction: 96.3
- Diagnostic accuracy: 96.1
- Pathologist responsiveness to problems: 93.6
- Pathologists’ accessibility for frozen section: 93.3
- Tumor board presentations: 93.1
- Courtesy of secretarial and technical staff: 93.0
- Communication of relevant information: 88.5
- Teaching conferences and courses: 88.2
- Notification of significant abnormal results: 86.3
- Timeliness of reporting: 79.8
Summer 2006
Understanding workflow in surgical pathology
The Problem
Tuesday afternoon and Wednesday morning, Aug 15-16, 2006

Specimens in Room 1, 7:00 am Wednesday morning – not accessioned

Cassettes awaiting processing, 7:00 am Wed morning

Batch processing!
Cross-Functional Design Team

Redesign process for gross examination of specimens to ensure continuous specimen flow, the right expertise for the right specimen at the right time, and support for tissue procurement.
Anatomic Pathology
Cross-Functional Design Team

- histotechnologists gross small specimens
- partner PA and resident for all services
partner PA and resident for all services in project scope

Grossing - AM
(9 am - 2 pm)

Grossing - PM
(2 pm - 7 pm)

Gross room

Mon Wed Fri
**Effective utilization of grossing stations (“benches”)**

<table>
<thead>
<tr>
<th>Room</th>
<th>Station 1</th>
<th>Station 2</th>
<th>Station 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room 1</td>
<td>GI</td>
<td>GU</td>
<td></td>
</tr>
<tr>
<td>Room 2</td>
<td>histotech</td>
<td>Breast</td>
<td>Derm</td>
</tr>
<tr>
<td>Room 2</td>
<td></td>
<td>GYN</td>
<td>M-Labs</td>
</tr>
</tbody>
</table>

**Workload leveling**
## Effective Utilization of Signout Rooms

<table>
<thead>
<tr>
<th>AM Signout (9 am-2 pm)</th>
<th>Room 1 (UH 1)</th>
<th>Breast</th>
<th>Derm</th>
<th>GI</th>
<th>GU</th>
<th>Renal</th>
<th>GYN</th>
</tr>
</thead>
<tbody>
<tr>
<td>DP (3MSI)</td>
<td></td>
<td></td>
<td></td>
<td>A</td>
<td>B</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PM Signout (2 pm-5 pm)</th>
<th>Room 1 (UH 1)</th>
<th>Breast (5MSI)</th>
<th>Derm</th>
<th>GI</th>
<th>GU</th>
<th>Renal</th>
<th>GYN (5MSI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DP (3MSI)</td>
<td></td>
<td>A (2UH)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B (2UH)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gyn (5MSI)</td>
</tr>
</tbody>
</table>

### Workload Leveling
Accession cases to specific faculty

- improve accuracy/efficiency of case tracking
- minimize case hand-offs
- drive expectations for case turnaround
### laboratory/transcription priorities aligned with service expectations

<table>
<thead>
<tr>
<th></th>
<th>Room 1</th>
<th>Breast</th>
<th>Derm</th>
<th>GI</th>
<th>GU</th>
<th>GYN</th>
<th>M-Labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross transcription</td>
<td>2:00 PM</td>
<td>8:00 AM</td>
<td>3:00 PM</td>
<td>1:00 PM</td>
<td>2:00 PM</td>
<td>8:00 AM</td>
<td>8:00 AM</td>
</tr>
<tr>
<td>completion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slide/Case Delivery</td>
<td>3:00 PM</td>
<td>9:00 AM</td>
<td>4:00 PM</td>
<td>2:00 PM</td>
<td>3:00 PM</td>
<td>9:00 AM</td>
<td>9:00 AM</td>
</tr>
<tr>
<td>completion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**workload leveling**
Anatomic Pathology
Design Team Recommendations April 2007

- histotechnologists gross small specimens
- partner PA and resident for all services
- stagger signouts for more effective utilization of grossing & signout space
- accession cases to specific faculty
- laboratory/transcription priorities aligned with service expectations
AP Laboratory Operations Group
Anatomic Pathology Implementation Plan

- Histotechnologists
  - training, competency documentation
  - incremental position

- PAs
  - realigned reporting relationships
  - new scheduling/staffing model

- policy development

- new functionality in LIS

- web-based calendars
Anatomic Pathology
Pre-Launch Communication

- project design team (Feb - Apr)
- AP Lab Operations Group
  Feb, Apr, May, Jun, Jul, Aug, Sep
- faculty meetings
  Jan, Feb, Apr, Jul, Sep
- AP Updates (weekly email “newsletter”)
  Jan, Feb, Mar, Apr, Jun, Jul, Aug, Sep
- residents’ luncheon
- accessioning & histology breakfast
GO LIVE!
create positive environment to minimize negative backlash
create space to openly share ideas as problems emerged

Support from the TOP!
PLAN
(identify, analyze)

DO
_design, implement_

CHECK
(evaluate)
Room 1 – NO, this isn’t a weekend, this is 1:00 p.m. on a Wednesday afternoon and NO BATCHED SPECIMENS! You just can’t make-up this kinda stuff – first day out of the chute and it’s working!

document early successes, failures and solutions
PLAN
(identify, analyze)

DO
(design, implement)

CHECK
(evaluate)

ACT
(adopt, standardize)
Anatomic Pathology
Turnaround Time (TAT) for Affected Rotations

Monthly Patient Volumes

Mean Turnaround Time (TAT)
Anatomic Pathology
Turnaround Time (TAT) for Affected Rotations

- Mean TAT (days)
- % Change

breast  GI  GYN  GU  derm (UMHS)  derm (MLabs)  UH ("bigs")  UH ("smalls")
Anatomic Pathology
Performance In Core Laboratories

Weekly Slide Delivery_Histology Lab_9-07 to 12-08

Avg=89.9%
LCL=74.2%

% on time slide delivery

Room 1 | Breast | Derm | GI | GU | GYN | M-Labs
---|---|---|---|---|---|---
Slide/Case Delivery (completion) | 3:00 PM | 9:00 AM | 4:00 PM | 2:00 PM | 3:00 PM | 9:00 AM | 9:00 AM
Anatomic Pathology
Staffing Efficiency

TOTAL OT HOURS FY '06-'09
AP DIVISION

UCL=989.7
Avg=572.8
LCL=155.9

AUG07
Anatomic Pathology
Gaps in Just-in-Time Processing

Accessioned Ungrossed Cases per Week

Avg=128.6
UCL=229.2
LCL=28

14-Apr-08 12-May-08 9-Jun-08 7-Jul-08 4-Aug-08 1-Sep-08 29-Sep-08 27-Oct-08 24-Nov-08 22-Dec-08
post-analytical phase errors

report delivery

clinical decision/action
Contrary to our original hypothesis, our modified anatomic pathology report formats reduced comprehension when compared to our hospital system’s standard report.

... The problem of report comprehension warrants exploration."
**Pathology Reports as Communication Tools**


**Fig 1. Original report format.**

**Fig 2. New report format.**

**Fig 3. Modernized report format.**

6 reports/3 formats questionnaire (each case) (yes, no, not stated)

**YALE - NEW HAVEN HOSPITAL ANATOMIC PATHOLOGY REPORT**

Patient: ___________________ Service: UROLOGY DEPT (YNHH)
Hospital # 1234567 Path # S94-12345
Birthdate: 02/08/28 (Age: 66)
Sex: M Physician: ____________
Accessioned on 08/30/94 UROLOGY 321 YPB
Reported on 09/01/94

Clinical Diagnosis and History:
CLINICAL IMPRESSION: PATIENT WITH BLADDER TUMOR AND PROSTATIC NODULE.

Tissue Source:
Part 1: TUR TUMOR TRIGONE BLADDER
Part 2: TUR BASE BLADDER
Part 3: BIOPSY LEFT BASE PROSTATE ...

**DIAGNOSIS:==========================================**

1) BLADDER, TRIGONE, TRANSURETHRAL RESECTION:
   -TRANSITIONAL CELL CARCINOMA, MODERATELY TO POORLY DIFFERENTIATED, GRADE III/IV
   -THE PATTERN OF GROWTH IS NODULAR AND PAPILLARY ...

2) BLADDER, BASE, TRANSURETHRAL RESECTION:
   -TRANSITIONAL CELL CARCINOMA, POORLY DIFFERENTIATED, GRADE IV/IV ...

6 reports/3 formats questionnaire (each case) (yes, no, not stated)

**YALE PATHOLOGY DEPARTMENT ANATOMIC PATHOLOGY REPORT**

Patient: ___________________ Service: UROLOGY DEPT (YNHH)
Hospital # 1234567 Path # S94-12345
Birthdate: 02/08/28 (Age: 66)
Sex: M Physician: ____________
Accessioned on 08/30/94 UROLOGY 321 YPB
Reported on 09/01/94

Diagnosis:
=====================================================

1) Bladder, Trigone, Transurethral Resection:
   -Transitional Cell Carcinoma, Moderately To Poorly Differentiated, Grade III/IV
   -The Pattern Of Growth Is Nodular And Papillary ...

2) Bladder, Base, Transurethral Resection:
   -Transitional Cell Carcinoma, Poorly Differentiated, Grade IV/IV ...

**GROSS DESCRIPTION** (Physician):
#1 - Received in formalin, labelled "tumor trigone bladder", are approximately 3 cc's of irregular tan-brown soft tissue fragments. They are submitted entirely.
#2 - Received in formalin, labelled "bladder tumor base", are ...

**PHYSICIAN RESPONSIBLE:**
Urology Dept (YNHH) 321 YPB

**PATHOLOGIST RESPONSIBLE:**
...
## Discordance Rates (%) by Report Format and Clinical Experience

<table>
<thead>
<tr>
<th></th>
<th>Original</th>
<th>Modernized</th>
<th>New</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Attending</strong></td>
<td>18</td>
<td>24</td>
<td>34</td>
<td>25</td>
</tr>
<tr>
<td>(n=15)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Housestaff</strong></td>
<td>26</td>
<td>32</td>
<td>34</td>
<td>31</td>
</tr>
<tr>
<td>(n=11)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Student</strong></td>
<td>33</td>
<td>28</td>
<td>48</td>
<td>37</td>
</tr>
<tr>
<td>(n=9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>All</strong> (n=34)</td>
<td>24</td>
<td>28</td>
<td>37</td>
<td>30</td>
</tr>
</tbody>
</table>
“Unfortunately, we found no reliable correlation between discordance and uncertainty.”
• diagnostic headlines to emphasize key points
• maintenance of layout continuity
• optimized information density
• reduction of “clutter”
• minimize corruption of formatting with report transmission
Pathology Reports as Communication Tools
Valenstein P. Arch Pathol Lab Med 2008; 132: 84

A

A. PROSTATE, RIGHT BASE: ATROPHY AND CHRONIC INFLAMMATION. NO NEOPLASM IDENTIFIED.
B. PROSTATE, RIGHT MID: ACUTE AND CHRONIC INFLAMMATION. NO NEOPLASM IDENTIFIED.
C. PROSTATE, RIGHT APEX: ATROPHY. NO NEOPLASM IDENTIFIED.
D. PROSTATE, LEFT BASE: ADENOCARCINOMA, CONVENTIONAL TYPE, GLEASON 3+4=7, SIZE = 7 MM, PERINEURAL INVASION PRESENT.
E. PROSTATE, LEFT MID: SINGLE FOCUS OF ADENOCARCINOMA, CONVENTIONAL TYPE, GLEASON 3+3=6, SIZE = 2 MM.
F. PROSTATE, LEFT APEX: ATROPHY AND CHRONIC INFLAMMATION. NO NEOPLASM IDENTIFIED.

B

PROSTATE: ADENOCARCINOMA
Malignant locations: left base, left mid
Benign locations: left apex, right base, right mid, right apex
Gleason score: 3 + 4 = 7
Size: 7 mm (left base); 2 of 6 cores contain carcinoma
Histologic type: conventional prostatic adenocarcinoma
Perineural invasion is present

C

ENDOMETRIUM: ADENOCARCINOMA.
Histologic type: Endometrioid
Histologic grade: Well differentiated (FIGO 1)
Non-malignant endometrium: Atypical hyperplasia
Endocervix: Not involved

D

ENDOMETRIUM: CANCER.
Cancer type: Adenocarcinoma
Histologic subtype: Endometrioid
Histologic grade: Well differentiated (FIGO 1)
Non-malignant endometrium: Atypical hyperplasia
Endocervix: Not involved

use of “diagnostic headline”

variation in information density
simplify and standardize reports, designed in collaboration with end users
### Customer Satisfaction in AP


<table>
<thead>
<tr>
<th>Service Category</th>
<th>Median (50th percentile)</th>
</tr>
</thead>
<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>
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<td>Notification of significant abnormal results</td>
<td>86.3</td>
</tr>
<tr>
<td>Timeliness of reporting</td>
<td>79.8</td>
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</tbody>
</table>
Designing for Safety in Surgical Pathology

Communicating ("Critical") Diagnoses

% of Respondents (n=73)*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Routine report delivery</th>
<th>Phone call within 24 hrs</th>
<th>Phone call ASAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasculitis</td>
<td>14%</td>
<td>31%</td>
<td>55%</td>
</tr>
<tr>
<td>Neoplasms causing paralysis</td>
<td>20%</td>
<td>20%</td>
<td>60%</td>
</tr>
<tr>
<td>New diagnosis of malignancy, with clinical suspicion</td>
<td>62%</td>
<td>28%</td>
<td>10%</td>
</tr>
</tbody>
</table>
“In today’s fractured patient care settings, with offsite pathology laboratories and specialized surgery centers, communication becomes an increasingly complex problem . . .

<table>
<thead>
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<th>Phone call within 24 hrs</th>
<th>Phone call ASAP</th>
</tr>
</thead>
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<tr>
<td><strong>New diagnosis of malignancy, with clinical suspicion</strong></td>
<td>62%</td>
<td>28%</td>
<td>10%</td>
</tr>
</tbody>
</table>
If our diagnosis fails to reach the appropriate medical provider, or the patient for that matter, should we agree that a routine but ‘missed’ cancer diagnosis \((\text{ie, one that is not acted upon because our report did not find the appropriate physician})\) becomes a critical value at some point in time?"

<table>
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</tr>
</tbody>
</table>
Critical Values Alerts Policy and Process

- Significant/unexpected diagnosis of malignancy (or vice versa) for which no equally timely and effective communication method exists
- Significant disagreement with outside interpretation of transfer cases for which no . . .
- Significant change in final versus frozen section diagnosis
- Amended report reflecting a significant change in diagnosis
- Clinically significant infections
- Unexpected absence of chorionic villi in uterine curettings
- Any findings likely to reflect either 1) unrecognized perforation of an organ, or 2) unintended surgical consequence/misidentification of a specimen
- Suspicion of wrong-site surgery
- Crescents in kidney biopsies
- Acute necrotizing vasculitis syndrome
Critical Values Alerts Policy and Process

- Significant/unexpected diagnosis of malignancy (or vice versa) for which no equally timely and effective communication method exists
- Significant disagreement with outside interpretation of transfer cases for which no...
- Significant change in final versus frozen section diagnosis
- Amended report reflecting a significant change in diagnosis
- Clinically significant infections
- Absence of chorionic villi in uterine curettings
- Findings likely to reflect either 1) unrecognized perforation of an organ, or 2) unintended surgical consequence/misidentification of a specimen
- Suspicion of wrong-site surgery
- Crescents in kidney biopsies
- Acute necrotizing vasculitis syndrome
## Number of reported events requiring action

<table>
<thead>
<tr>
<th>Year</th>
<th>QTR1</th>
<th>QTR2</th>
<th>QTR3</th>
<th>QTR4</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>2008</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2009</td>
<td>0*</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*YTD
Designing for Safety in Surgical Pathology

Countermeasures for Post-Analytical Errors

- simplify and standardize reports, designed in collaboration with end users
- critical values alerts policy
• formal written plan for error detection and problem resolution
• application of Lean principles and tools
• electronic positive patient identification at multiple fiduciary tracking points
• aspire to a culture of safety
communication across authority gradients
error reporting
report delivery
• forced functions predicated on specific QA initiatives (selected prospective re-review)
• real-time monitoring of diagnostic trends
• delivery of “just-in-time” case specific content
• commitment to service
• formal written plan for error detection and problem resolution
• application of Lean principles and tools
• provider order entry
• electronic positive patient identification
• software solutions that maintain fidelity of patient ID across key handoffs
At the end of this lecture attendees will be able to,

- understand the problem of safety and quality in surgical pathology
- understand the value of systems-based thinking in addressing challenges in safety & quality
- identify specific solutions to common problems in surgical pathology quality and safety