Committee on Diagnostic Error in Health Care
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NO RELEVANT RELATIONSHIPS TO DISCLOSE

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Diagnostic Errors in (. . . and around) Pathology

Introduction
Committee questions
Summary
Discussion
but is pathology a problem?
Five Chilling Real-Life Stories

“the surgeon called Kastrup into her office and confessed that the lymph nodes had never made it to the lab”
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.
“... the sample her diagnosis was based on had been contaminated with cancerous cells from another patient’s specimen”
What if the Doctor Is Wrong?
Some Cancers, Asthma, Other Conditions Can Be Tricky to Diagnose, Leading to Incorrect Treatments

When a CT scan showed multiple tumors in Dawna Harwell’s pelvis, abdomen and spine in 2008, her doctors in Dallas told her she might have ovarian cancer, which can be especially deadly.

A biopsy came back with inconclusive results, and Ms. Harwell wasted no time in seeking a second opinion at MD Anderson Cancer Center in Houston. “I went through every test in the book,” says Ms. Harwell. Still, doctors couldn’t be sure what she had. Finally, she underwent a surgical procedure to diagnose her case: It wasn’t ovarian cancer after all, but a rare form of lymphoma. The 47-year-old horse trainer in Collinsville, Texas, underwent a rigorous regimen of chemotherapy that ended last spring. At her first six-month checkup in October, she received a clean bill of health.

Evidence is mounting that second opinions—particularly on radiology images and pathology slides from biopsies—can lead to significant changes in a patient’s diagnosis or in recommendations for treating a disease. Some malignancies, including lymphomas and rare cancers of the thyroid and salivary glands, are notoriously tricky to diagnose correctly; test results can be inconclusive or return false results. After a decade of annual mammograms, more than half of women...
“the error rate in laboratory medicine ranges from less than 0.05% up to 10%, depending on the wide variety of definitions, the methods for identifying error frequency and nature and the type of healthcare facility.”

“The great majority of these errors, however, occur for individual or system design defects in extra-analytical phases of the total testing process”

“In a subgroup analysis of major diagnostic errors (n=162), 43% were related to clinician assessment and 42% to laboratory and radiology testing.”

2nd place – failure/delay in ordering needed test (12%)

3rd place – failed/delayed follow-up of abnormal test result (9%)

†Schiff et al. Arch Intern Med 2009; 169: 1881
Diagnostic Errors in Medicine
Analysis of UMHS “Diagnostic Errors”

July 1, 2012 – July 31, 2014

Contributing Factors (n = 248)
- misinterpretation of test results (6.5%)
- test results not reviewed (3.2%)
- test results not available (1.2%)

Reporting Locations (n = 139)
- emergency department – adult (24.5%)
Diagnostic Errors in ( . . . and around) Pathology

Introduction

Committee questions
What system changes can be implemented to reduce diagnostic errors in the laboratory, including errors in the pre-analytic, analytic, and post-analytic phases?

computerized provider order entry (CPOE)
## Error Reduction Tactics in Pathology

**Computerized Provider Order Entry (CPOE)**

<table>
<thead>
<tr>
<th>Provider</th>
<th>Laboratory</th>
<th>Provider</th>
</tr>
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<tbody>
<tr>
<td><strong>Before CPOE</strong></td>
<td>req + specimen</td>
<td>order entry</td>
</tr>
<tr>
<td><strong>After CPOE</strong></td>
<td>CPOE printed order + specimen</td>
<td>order reconciliation</td>
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“Our rates of missed test results are lower than those reported from studies where paper ordering and reporting systems were used. This suggests that the availability of CPOE systems may reduce the risk of these events.”

Error Reduction Tactics in Pathology

Computerized Provider Order Entry (CPOE)†

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Organizational Dysfunctions
- ↓ scrutiny of orders
- ↑ unfulfilled orders
- ↑ potential for errors
- add-on tests unclear
- collection time discrepancies

What system changes can be implemented to reduce diagnostic errors in the laboratory, including errors in the pre-analytic, analytic, and post-analytic phases?

- specimen tracking
- real-time monitoring of specimen progression
Error Reduction Tactics in Pathology
Computerized-Assisted Bar-Coding/RFID†

EPPID = electronic positive patient identification

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

Error Reduction Tactics in Pathology
Computerized-Assisted Bar-Coding/RFID†

†from Shim et al. J Med Syst 2011; 35: 1403
Error Reduction Tactics in Pathology
Computerized-Assisted Bar-Coding/RFID†

<table>
<thead>
<tr>
<th>Class</th>
<th>Pre-RFID</th>
<th>Post-RFID</th>
</tr>
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<tbody>
<tr>
<td>Class 1</td>
<td>7.85%</td>
<td>0.41%</td>
</tr>
<tr>
<td>Class 2</td>
<td>1.36%</td>
<td>0.12%</td>
</tr>
<tr>
<td>Class 3</td>
<td>0.09%</td>
<td>0.02%</td>
</tr>
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</table>

Class 1 – typographical
Class 2 – minor error
Class 3 – major error with harm

†from Francis et al. Am J Gastroenterol 2009; 104: 972
Error Rates in Pathology
Specimen Identification Defects†

6,577 ID defects in 4,827 specimens

Error Rates in Pathology
Specimen Identification Defects†

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

†from Makary et al. Surgery 2007; 141: 450-5.

process improvement opportunities
What system changes can be implemented to reduce diagnostic errors in the laboratory, including errors in the pre-analytic, analytic, and post-analytic phases?

standard process for specimen submission
How can clinician training in appropriate test ordering and interpretation be improved?

Strategies that engage the expertise of laboratorians may offer more robust sustainable solutions than clinician training.
Pathologist Michael LaPosata, M.D., Delivers the Message about Diagnostic Management Teams and Clinical Laboratory Testing to Attendees at Arizona Meeting

PHOENIX, ARIZONA—Most pathologists and clinical laboratory scientists are quick to agree that overutilization of medical laboratory tests is a major problem in healthcare. But underutilization of medical lab tests is an equally significant problem. That’s the message delivered here last Monday by pathologist Michael LaPosata, M.D., Ph.D., during a presentation he delivered at the Sunquest Executive Summit.

LaPosata, who recently assumed new duties as the Chair of Pathology at the University of Texas Medical Branch in Galveston, Texas, was speaking about the value of what he calls “diagnostic management teams,” or DMTs. In recent years, while at Vanderbilt University Medical Center, LaPosata and his colleagues introduced DMTs in support of several medical specialties. These DMTs proved quite successful at improving patient outcomes, while reducing the overall cost per healthcare encounter for these patients.

Unaddressed Issues in Clinical Laboratory Medicine

Dark Daily would like to highlight a few of the unaddressed issues currently practiced today, which were discussed by LaPosata. These exist for clinical pathologists and laboratory scientists to be addressed these issues within their hospitals and clinical labs will provide the characteristics of a DMT as described by LaPosata.

“diagnostic specialists from the care team and from pathology routinely convene and synthesize their findings and establish diagnoses”

†Michael LaPosata, Dark Daily July 21 2014.
“If you are seriously ill with an unknown diagnosis, you want,

• an expert in the field
• with current knowledge
• directing your evaluation in real time and explaining it all to you.

This is the diagnostic management team”

†Michael Laposata, Dark Daily July 21 2014.
How can reporting of results be improved to prevent missed follow-up and improper interpretation?

- engaging laboratorians as integrated members of care team
- standardized expectations for locally crafted policies defining significant and urgent results as well as accountable providers and chain-of-command for results communication

Error Reduction Tactics in Pathology
Closed Loop Communications Systems

- computerized notification systems

- inpatient call centers†
- EHR data mining solutions‡

Diagnostic Errors in (. . . and around) Pathology

How can reporting of results be improved to prevent missed follow-up and improper interpretation?

- engaging patients in ordering & reporting processes
- redesigning response strategies to shift greater responsibility to the laboratory for follow-up care.

from Philip Chen, Sonic Healthcare USA, APC/PRODS, July 2013
What are the opportunities and challenges in using technology to improve diagnosis in pathology (decision support tools to aid in test selection, results management and reporting, etc.)?

Decision support tools have demonstrated potential to mitigate vulnerabilities in pre-analytical and post-analytical phases of testing.
Error Reduction Tactics in Pathology: Decision Support Tools In Pre-analytic Phase

- “smart” EHRs that reconcile test results with patient data

“Based on this patient’s clinical and diagnostic profiles and the past laboratory records, . . . recommends the following tests at this time.”

- designing for human factors

from Philip Chen, Sonic Healthcare USA, APC/PRODS, July 2013
Computer aided diagnostic tools aim to empower rather than replace pathologists: Lessons learned from computational chess

Jason Hipp, Thomas Flotte¹, James Monaco², Jerome Cheng, Anant Madabhushi², Yukako Yagi³, Jaime Rodriguez-Canales⁴, Michael Emmert-Buck⁴, Michael C. Dugan⁷, Stephen Hewitt⁴, Mehmet Toner⁵, Ronald G. Tompkins⁵, David Lucas, John R. Gilbertson⁶, Ulysses J. Balis
Diagnostic Errors in ( . . . and around) Pathology

Can evidence-based guidelines, standards, or metrics be incorporated into practice to reduce diagnostic error? What is the role of competency assessment of laboratory personnel in preventing diagnostic errors?

- standardized report content and format—an expectation of practice
- effective peer review driven by locally derived data identifying practice vulnerabilities
Quality and safety is a problem of **WHY** not a problem of **WHO**.
Should autopsy remain the “gold-standard” in diagnostic error detection? If so, what changes could promote the performance of autopsies?

“The possibility that a given autopsy will reveal important unsuspected diagnoses has decreased over time, but remains sufficiently high that encouraging ongoing use of the autopsy appears warranted.”

“we estimated that a contemporary US institution (based on autopsy rates ranging from 100% [the extrapolated extreme at which clinical selection is eliminated] to 5% [roughly the national average]), could observe a

• **major error rate** from 8.4% to 24.4% and a

• **class I error rate** from 4.1% to 6.7%.”

## Error Reduction Tactics in Pathology

### Autopsies as Error Detection Resource

<table>
<thead>
<tr>
<th>Class</th>
<th>2011–2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>11 (1.8%)</td>
</tr>
</tbody>
</table>

### Class I
- Detection before death, in all probability, would have led to a change in management that might have resulted in cure or prolonged survival.

### Class II
- Detection before death would probably have not led to a change in management (*e.g.*, no good therapy available, already received appropriate therapy, patient refused therapy).

### Class III–IV
- Related to the terminal disease process but not directly related to death (III); incidental findings not related to terminal disease process (IV).
“Failure to adjust for the prevalence of missed cases among non-necropsied deaths may substantially overstate the performance of diagnostic tests and antemortem diagnosis in general, especially for conditions with high early case fatality.”

Should autopsy remain the “gold-standard” in diagnostic error detection? If so, what changes could promote the performance of autopsies?

YES!

- sustainable business model
- accreditation standards equivalent to other diagnostic services
Diagnostic Errors in (. . . and around) Pathology

What research is needed to better understand and identify how anatomic/clinical pathology practice contributes to the problem of diagnostic error? How can this research lead to improvements in practice?

1. Impact of CPOE on diagnostic errors.
2. Impact of alternative care models of test ordering and reporting that integrate laboratorians into care teams and engage patients and families as direct participants.
3. Relationship between diagnostic variance for interpretive results and patient outcomes.
4. Impact of CAD on diagnostic accuracy in high value targets (eg, cancer).
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Every system is perfectly designed to achieve exactly the results it gets.

Don Berwick’s “Central Law of Improvement”
# Factors Associated with High Performance in Quality and Safety†

<table>
<thead>
<tr>
<th>High-Impact Leadership Behaviors</th>
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<tbody>
<tr>
<td>1. Person-centeredness</td>
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<tr>
<td>Be consistently person-centered in word &amp; deed.</td>
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<tr>
<td>2. Front line engagement</td>
</tr>
<tr>
<td>Be a regular authentic presence at the front line &amp; a visible champion of improvement.</td>
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<tr>
<td>3. Relentless focus</td>
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<tr>
<td>Remain focused on the vision and strategy.</td>
</tr>
<tr>
<td>4. Transparency</td>
</tr>
<tr>
<td>Require transparency about results, progress, aims and defects.</td>
</tr>
<tr>
<td>5. Boundarilessness</td>
</tr>
<tr>
<td>Encourage and practice systems thinking and collaboration across boundaries.</td>
</tr>
</tbody>
</table>

† Swensen et al. High-Impact Leadership: Improve Care, Improve the Health of Populations, and Reduce Costs. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2013. (Available at ihi.org)
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