Diagnostic Error & Laboratory Testing

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Founder and President:
Society to Improve Diagnosis in Medicine
Two Different Worlds
Missed Diagnosis of Wegener’s

CC: 67 YOM with 3 weeks of fever, cough, and a painful ulcer on the tongue

LAB: ↑ WBC, ↓ RBC, ↑ BUN, hematuria, infiltrates on CXR

IMP: ER Diagnosis: Pneumonia   ICU Diagnosis: Same

COURSE: The patient was admitted to the ICU and started on IV antibiotics. The patient’s oxygenation deteriorated, serum BUN & creatinine were rising. On Day 3, a Nephrology consultant suggested the possibility of Wegener’s granulomatosis and an ANCA was ordered. The test result was not available the next day, or the day after that. On Day 6 the patient developed massive hemoptysis and expired. The test (run post-mortem) was ++++ and autopsy was consistent with a necrotizing vasculitis.
Fact finding:

ANCA testing is a ‘send out’
All ‘send out’s’ require a special request
The sample was being held in the lab until the form was completed
The resident’s didn’t know any of this
The lab sent an email to the residents
The residents don’t read their VA email
The lab is 20 feet from the ICU
CLIA (1967, 1988)
CDC Survey (1950)

SAFETY & QUALITY

Journals, conferences, programs, certifications, standards, monitors, training, ....

Lab Error

500 BC

Dx Error in Medicine

0

1900

1950

2000

2010

SIDM (2011)
DEM (2008)
IOM (1999)
NPSF (1997)
Diagnostic Errors

Falls

Med Errors

Wrong Site Surgery
DIAGNOSIS

THE PAST

DRIVERS

THE FUTURE

Patient Engagement Movement

Awareness of Dx Error - SIDM

IOM – Report due 2015
Diagnostic Error Rate Estimates

- **Expert estimate**: 10-15% estimate by Arthur Elstein
- **Second reviews**: 2-5% of abnormalities are missed by radiology and pathology
- **Standardized patients**: 13% of patients presenting with common conditions (COPD, RA, others) are missed
- **Look backs**: Cervical cancer: 25-50% of last normal PAP are abnormal on review
- **Autopsies**: 10-20% of autopsies reveal major unexpected diagnoses that would have changed the management

The toll of Dx Error

US

40,000 – 80,000 deaths/yr

1 in 20 primary care visits involves a preventable dx error; half are potentially harmful

Leape et al. JAMA 288:2405, 2002

Your Hospital

10 deaths every year

10 patients harmed every day in your clinics or ER

Where are Diagnostic Errors Encountered?

ED: 16%
Inpatient: 28%
Ambulatory: 56%

Dana Siegel; CRICO-RMF 2014
CBS N=4,519 PL cases closed 1/1/08–12/31/12 with a diagnosis-related major allegation.
Diagnosis is HARD!

PATIENT VARIABLES
- Stage of disease
- How it manifests
- How it is perceived
- How it is described
- When help is sought

PHYSICIANS VARIABLES
- Knowledge and experience
- Access to patient data, tests, consults
- Skill in clinical reasoning
- Stress, distractions, mood, time to think

SYSTEM COMPLEXITY
- Disjointed care
- Communication barriers
- Production pressure
- Tight coupling
- Access to care & expertise
How Many Diseases are There?

World Health Organization:
- ICD 8 1965 1000
- ICD 9 1979 8000?
- ICD 10 1999 12,420

NLM: 8000 MESH Growing at 200+ terms
Cumulative Number of Tests Categorized Over Time

- 7/1993 – 12,137
- 1/2000 - 25,708
- 2/2008 - 39,428

Colors:
- Waived
- Moderate
- High
DIAGNOSTIC ERROR
(Wrong, missed & delayed diagnosis)

Process Errors
- Cognitive
- System-Related

All Other Causes

Inconsequential

HARM
Harm 44%

10%

The Total Testing Process

Ordering
Collection
Identification
Transportation
Preparation

Analysis

14%
< 0.1%

Error rate

Reporting
Interpretation
Action

7.5%
Common Problems
Analytic Phase

• **Test interference** – false positive and negative results

• **Send out testing** – delayed results; results not interfaced to LIS; results don’t reach current provider

• **Cytology & pathology error**
  2- 4% missed or wrong malignancies
Bedside Testing

An 75 YOM was admitted for an exacerbation of COPD. He was incidentally found to have mild anemia and thrombocytopenia (Platelets = 77,000 / mm3). The admitting resident ascribed this to asymptomatic cirrhosis.

The attending physician for this patient happened to be a hematologist, who prepared and examined a blood smear, which showed classic change of myelodysplastic syndrome.

A survey of the 12 medical residents on the wards that month revealed that they routinely read ECG’s, but in the past year none had done their own urinalysis, reviewed a blood smear, or performed a gram stain. 10 were unaware of the house-staff lab around the corner from the wards. Only 1 in 10 will see an autopsy.
Common Problems
Outside Lab Walls

Pre-pre-Analytical
• MD doesn’t know best test
• Test was already done
• Orders miscommunicated
• Patient doesn’t have test done

Post-post-Analytical
• Delayed test results
• MD misinterprets results
• Results never reviewed or never acted upon
• Patient unaware of results
“It’s a simple stress test—I do your bloodwork, send it to the lab, and never get back to you with the results.”
Notification of Abnormal Lab Results

Studied 4 alerts:

A1c > 15%, Hep C Ab positive;
PSA > 15 ng/ml, TSH > 15 mIU/L

Of 78,158 tests done over 6 months, 1163 were critical abnormals sent as alerts

10% never acknowledged; 7% no evidence of follow-up within 30 days.

“I wish I had seen this test result earlier!”

- Survey of 262 internists
- They reported spending 74 minutes/day managing test results
- 83% reported at least one unacceptable delay during the previous 2 months

EG Poon et al. Arch Intern Med 164: p2223-8, 2004
Patient safety concerns arising from test results that return after hospital discharge

• Reviewed the records of all 1095 patients discharged over a 5 month period.

• 2033 results returned after discharge. 191 were judged to be actionable.

• Physicians were unaware of 65 (62%)
Diagnostic Error
Root cause analysis

Patient’s Clinical Course

BLUNT end

Communication, coordination, training, policies, procedures

SHARP end

Cognitive

SYSTEM

Me
Missed Diagnosis of Wegener’s

Cognitive Errors
- Knowledge: OK
- Data collection: Faulty
- Synthesis: Context error & Premature closure

System Errors
- LAB: Wrong assumption that providers know all the lab rules & that email was an effective communication route. Cumbersome process for a test needed STAT. Too removed from the clinical situation.
- PROVIDERS: False assumptions that the test results would be back ‘any minute’. Failure to follow up on the test, or to discuss their needs with the lab. Suboptimal trainee supervision.
Etiology of Diagnostic Error

- Both System and Cognitive Errors: 46%
- No Fault Error Only: 7%
- System Error Only: 19%
- Cognitive Error Only: 28%
Cognitive Errors: 320

Faulty Synthesis 83%
Faulty Knowledge 3%
Faulty Data Gathering 14%
Diagnostic Error – System Factors

215 system factors in the 100 cases

- Problems related to coordination and communication
- Lack of available expertise
- Breakdowns related to diagnostic testing
COGNITIVE ERRORS (n = 320)

Most common:

• Premature closure
• Faulty context or framing error
• Faulty perception
“Say ... What's a mountain goat doing way up here in a cloud bank?”
Premature closure = Satisficing

= Falling in love with the first puppy ...

( Herbert Simon )
"It's tough to make predictions, especially about the future."
Yogi Berra

**Good News**

- Lab testing is ever more reliable (ANALYTICAL)
- Maturing sciences of ...
  - Quality improvement
  - Clinical reasoning
  - Wrongology
- Prevention strategies are emerging
  - Simulation
  - Second opinions
  - Decision support
  - RCA’s, QI
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Bad News

- Risks are INCREASING for PRE- and POST-ANALYTICAL
- New trainees seem increasingly LESS interested in the lab
- The distance between the lab and clinicians is growing
Risk of Dx Error from Lab Testing

Pre-pre, Post-post

Analytical
General Solutions for Dx Error

COGNITIVE

Increase access to knowledge & data

Use EBM; Use simulation

Decrease reliance on intuition by
• Second opinions
• Decision support
• Feedback & follow-up

SYSTEM-RELATED

Relentless quest for quality

EMR’s; Decision support

Make sure expertise is available when needed

Increase resiliency – involve the patient
Specific Solutions: Lab-Related Error

**Frontline Providers**

- Learn about lab tests
- Have a reliable process to ensure ordered tests are done and reviewed
- Always assign a surrogate if you will be away
- Find a partner in the Lab and in Radiology
- Use online resources to guide appropriate test ordering and interpretation

**The Clinical Lab**

- Focus on finding and fixing pre- and post-analytical errors
- Identify a clinical liaison person
  - Simplify test ordering
  - Use order sets
  - Use reflexive testing
- Address cognitive error – Get second opinions
- Improve test reporting: Better comments, display trends
US Autopsy Rates

Bring it Back !!!
Second Opinions

HAS YOUR DIAGNOSIS HAD ITS CHECK-UP?

WHEN YOU NEED TO BE SURE, CALL BEST DOCTORS.
Survey of 252 pathologists

- 81% obtain second opinions (though policies vary)
- 96%: Improve accuracy and protect against malpractice suits
- 66%: Easy to obtain
- 85%: Did not take too much time
5 year look-back at the Mayo Clinic of 71,811 cases
  – 457 major disagreements (0.6%)
  – Of these: 90% involved a major change of treatment or prognosis

• Of 166 cases with tissue follow-up: second opinion correct in 85%

Valenstein: $23,000/disagreement
Look back at 1499 patients
  – 394 major disagreements (26%)

• Of these disagreements, on follow-up:
  – 69% agreement with second opinion
  – 24% agreement with the first opinion
CAP/ADASP:
Interpretive Diagnostic Error Reduction Project

Raouf Nakhleh, MD, CAP co-chair
Vania Nosé, MD, PhD, ADASP co-chair
Purpose

• The purpose of this guideline is to systematically examine the literature concerning second reviews of cases with the goal of establishing procedures that optimize the use of these additional case reviews in order to reduce interpretive errors or discrepancies.
Key Questions

1) Does targeted review (either done at analytic or post-analytic phase) of surgical pathology or cytopathology cases (slides and/or reports) reduce the error rate (often measured as amended reports) or increase the rate of interpretive error detection compared to no review, random review or usual review procedures?

2) What methods of selecting cases for review have been shown to increase/decrease the rate of interpretive error detection compared to no review, random review or usual review procedures?
Literature Review

- **37 Multi-organ studies**
  - 30 Surgical pathology
  - 3 Cytology
  - 4 Both

- **111 Single-organ studies**
  - Surgical pathology
    - Prostate 18
    - Melanoma/skin 11
    - GU 7
    - Liver & GI 7
    - Non-cervical GYN 7
    - Soft tissue and bone 7
    - ENT, lymphoma, neuropath, breast
  - Cytology
    - Thyroid 8
    - GYN 3
    - Pancreas/biliary 2, lung 1, effusions 1, urine 1
  - Both
    - GYN 2, anal 1, Lung 1
Recommendation 1

1. Anatomic pathologists should develop procedures for review of selected pathology cases to detect disagreements and potential interpretive errors and improve patient safety
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Two Different Worlds ....

But partners in reducing Dx Error