

# Diagnostic Error & Laboratory Testing

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**Founder and President:**

**Society to Improve Diagnosis in Medicine**



**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.

# Missed Diagnosis of Wegener's

## 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)**



**SIDM (2011)**

**DEM (2008)**

**IOM (1999)**

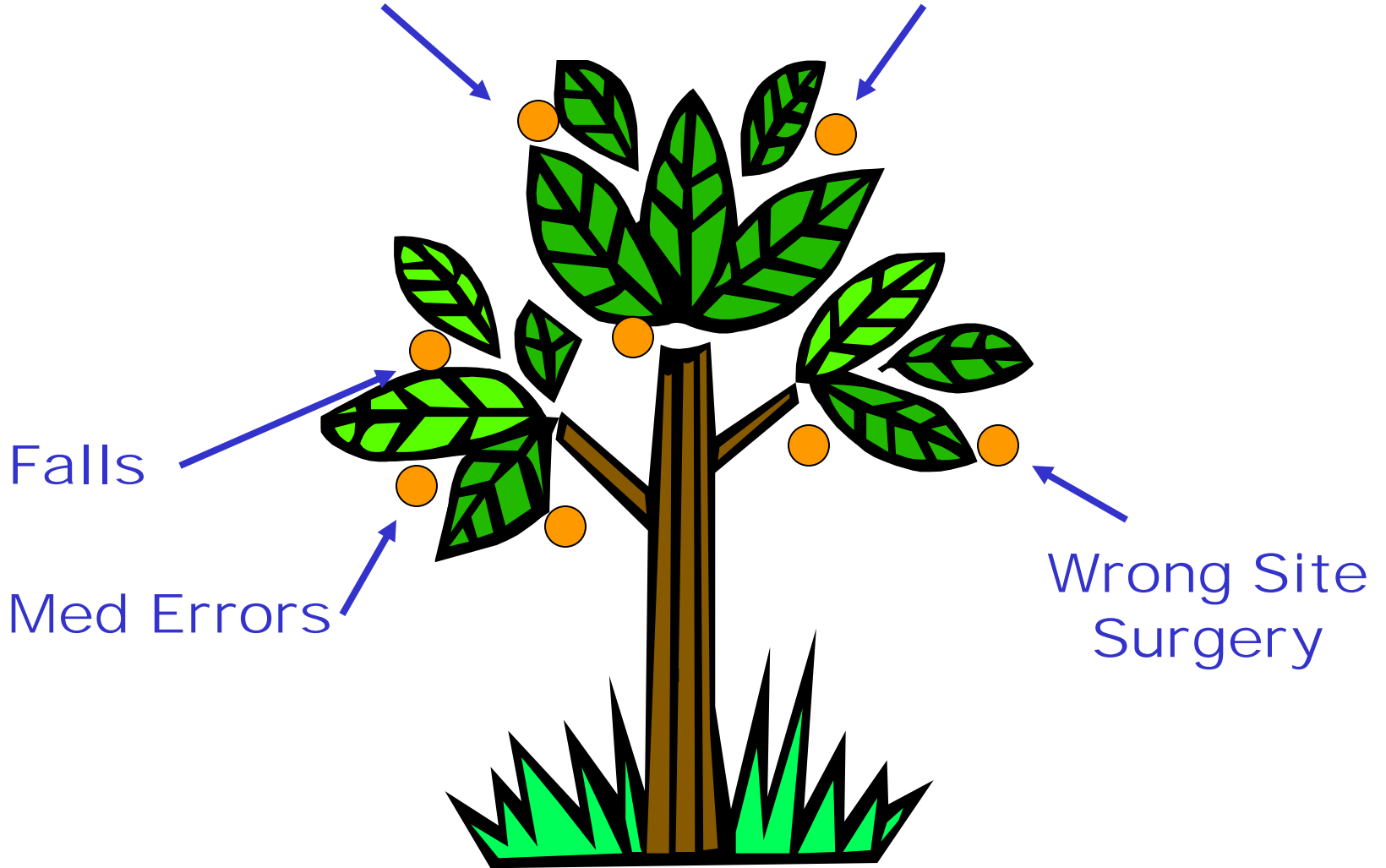
**NPSF (1997)**

**Lab Error**

**500 BC**

**Dx Error in Medicine**

Diagnostic Errors



THE PAST

**DIAGNOSIS**



THE FUTURE

**DRIVERS**

**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**

**Your Hospital**

**40,000 – 80,000**

**10 deaths every year**

**deaths/yr**

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

**10 patients harmed every day in your clinics or ER**

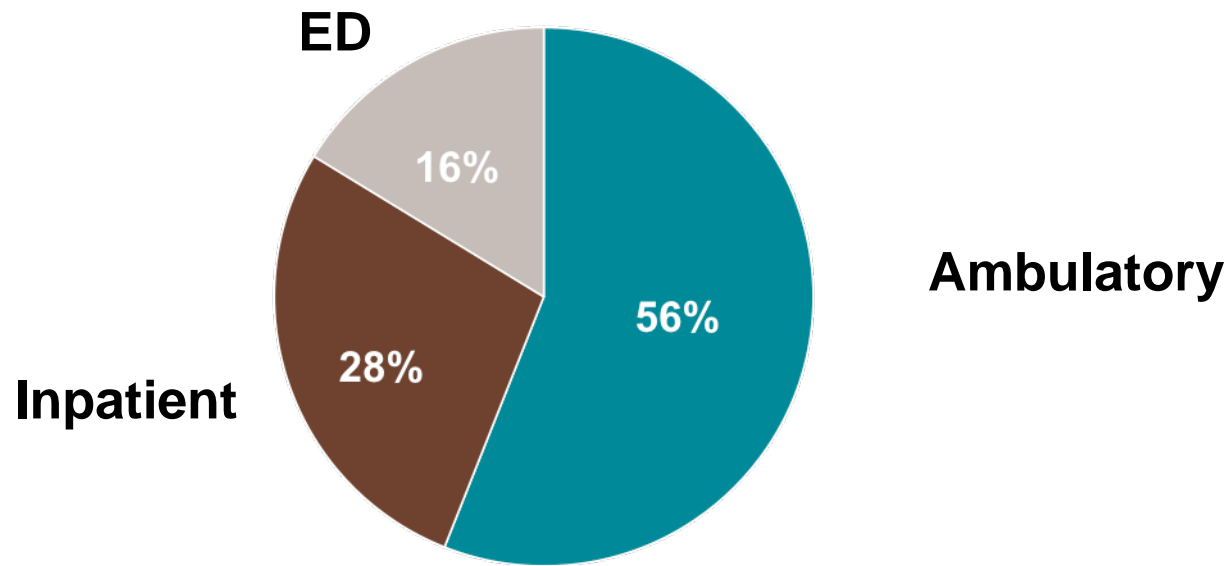
**Error-related Harm**

**Diagnostic Error**

Leape et al. JAMA 288:2405, 2002

Singh et al. BMJ Qual Safety 21: 93-100, 2012

## Where are Diagnostic Errors Encountered?



**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

## PHYSICIAN 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:

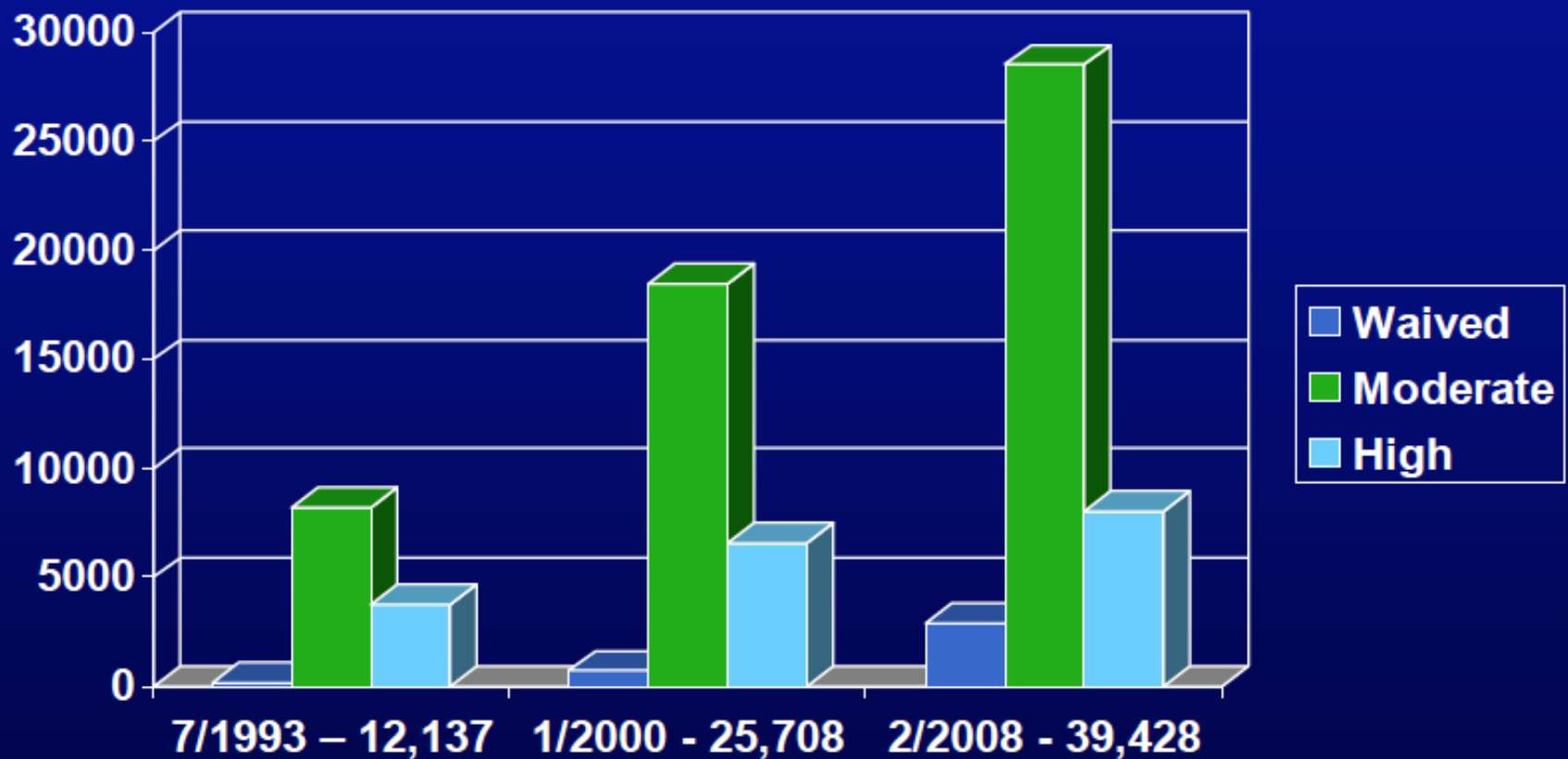
- ICD 8      1965                      1000
- ICD 9      1979                      8000?
- ICD 10     1999                     12,420



**NLM: 8000 MESH**  
**Growing at**



# Cumulative Number of Tests Categorized Over Time



**Process Errors**

**All Other Causes**

**System-Related**

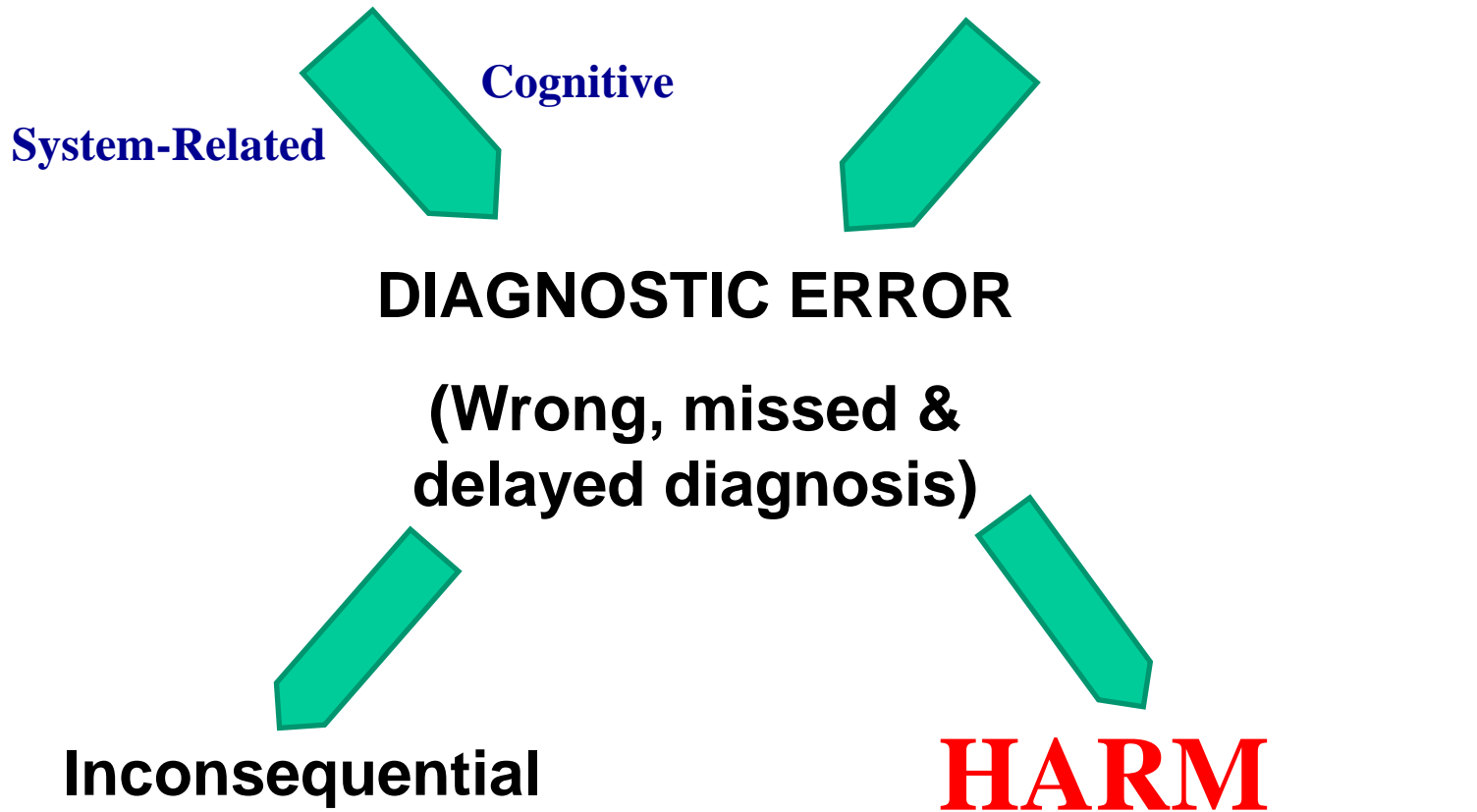
**Cognitive**

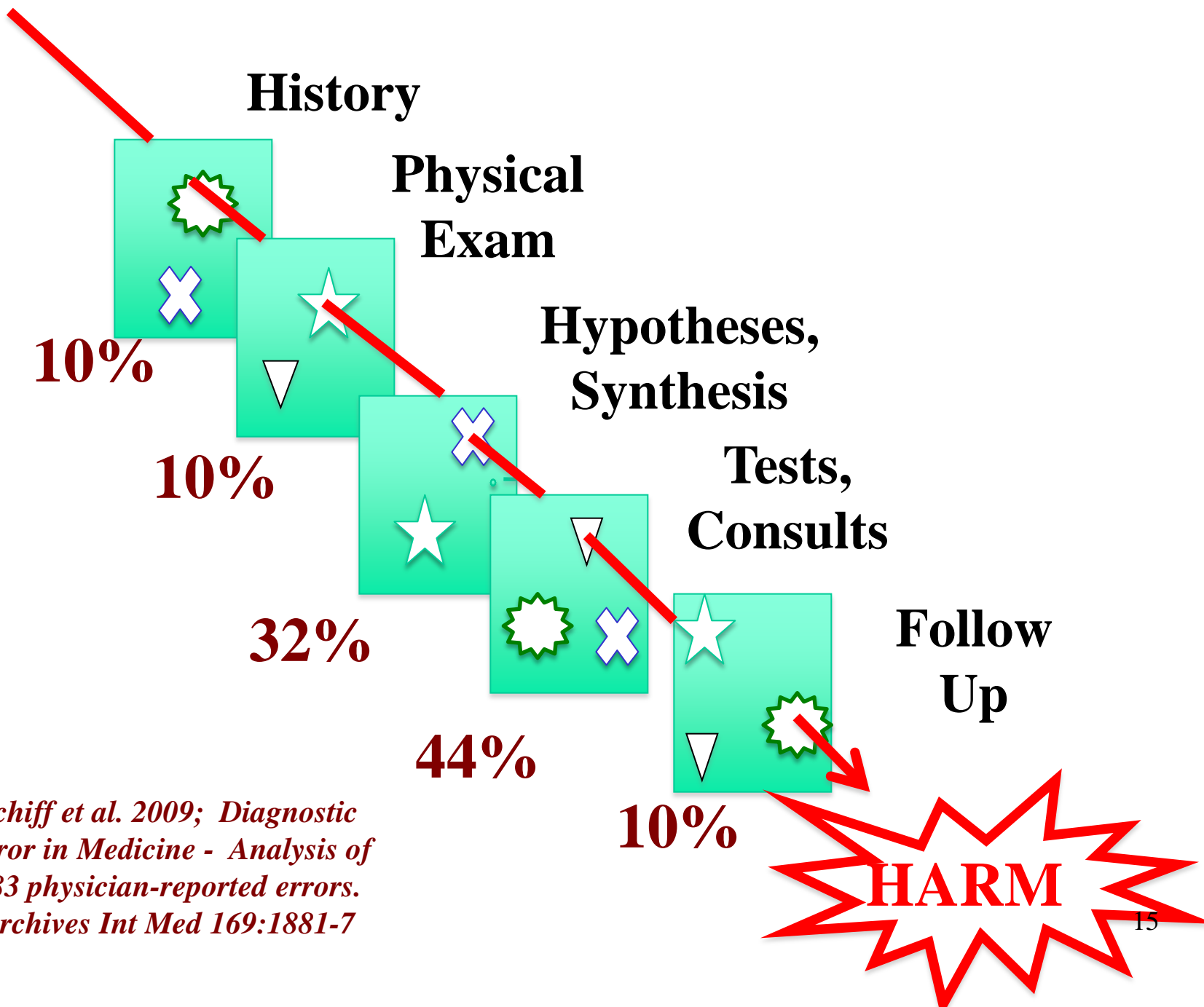
**DIAGNOSTIC ERROR**

**(Wrong, missed &  
delayed diagnosis)**

**Inconsequential**

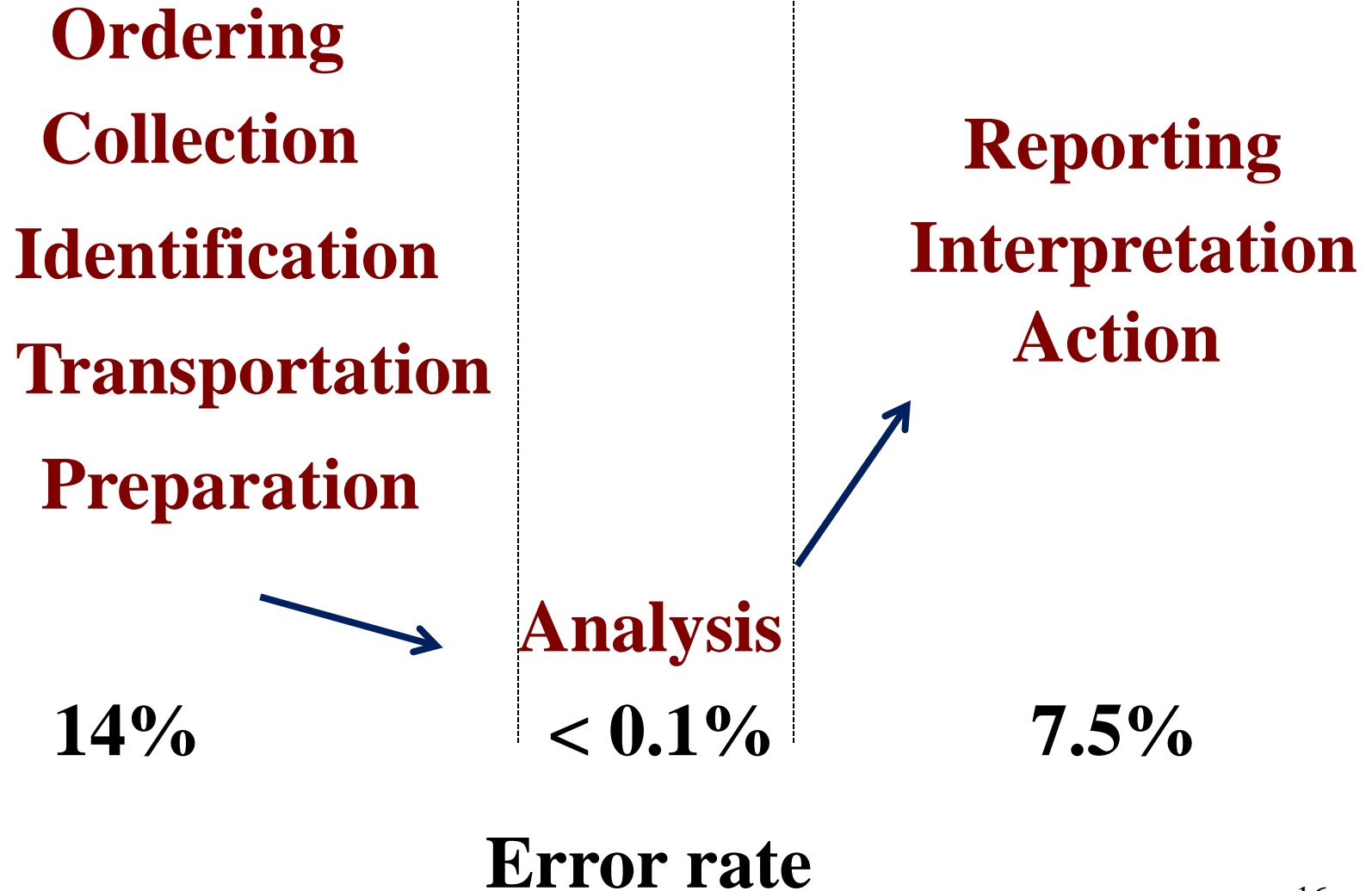
**HARM**





*Schiff et al. 2009; Diagnostic Error in Medicine - Analysis of 583 physician-reported errors. Archives Int Med 169:1881-7*

# The Total Testing Process





# 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 / mm<sup>3</sup>). 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.**

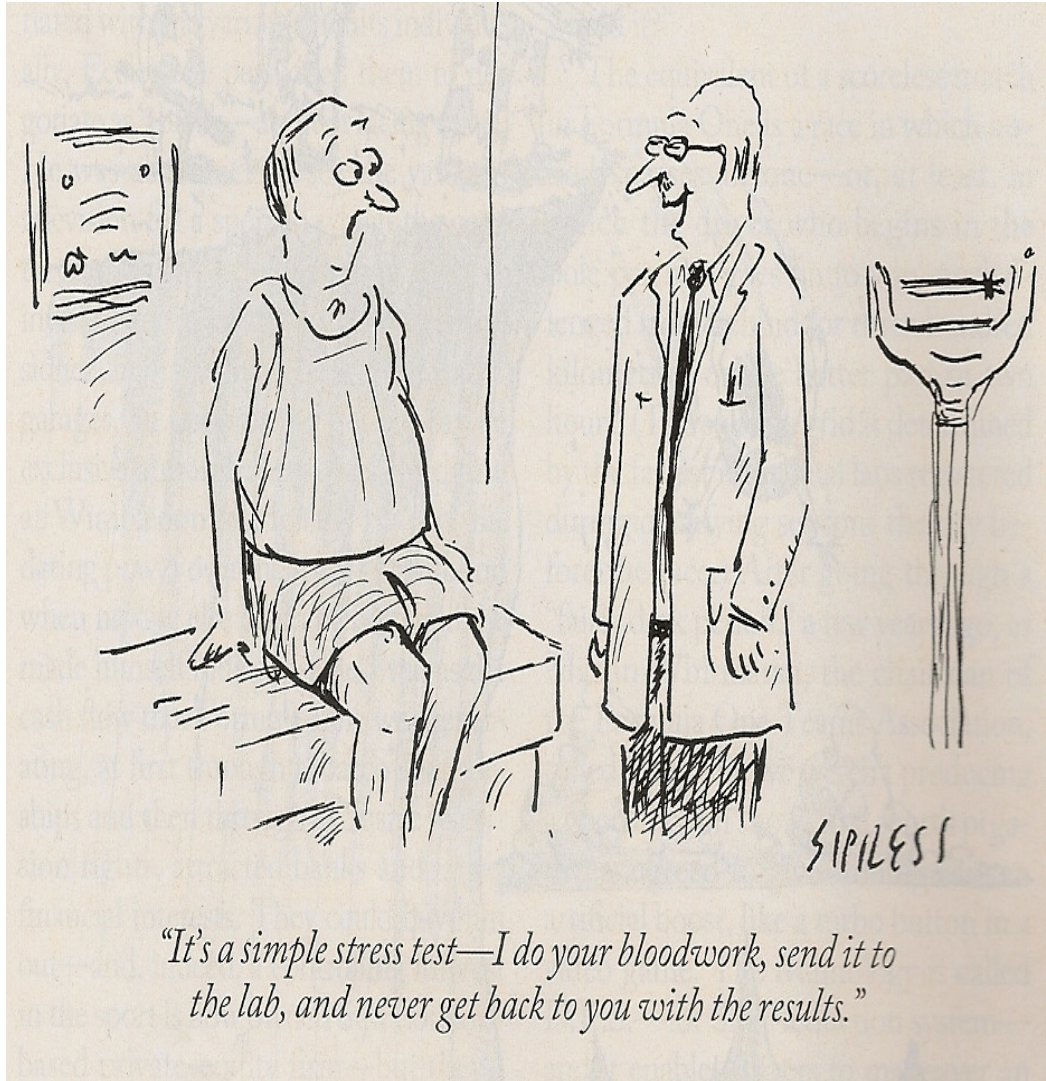
# Common Problems Outside Lab Walls

## 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 abnormalities sent as alerts**

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

*Singh et al. Am J Med 2010; 123:238-44*

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

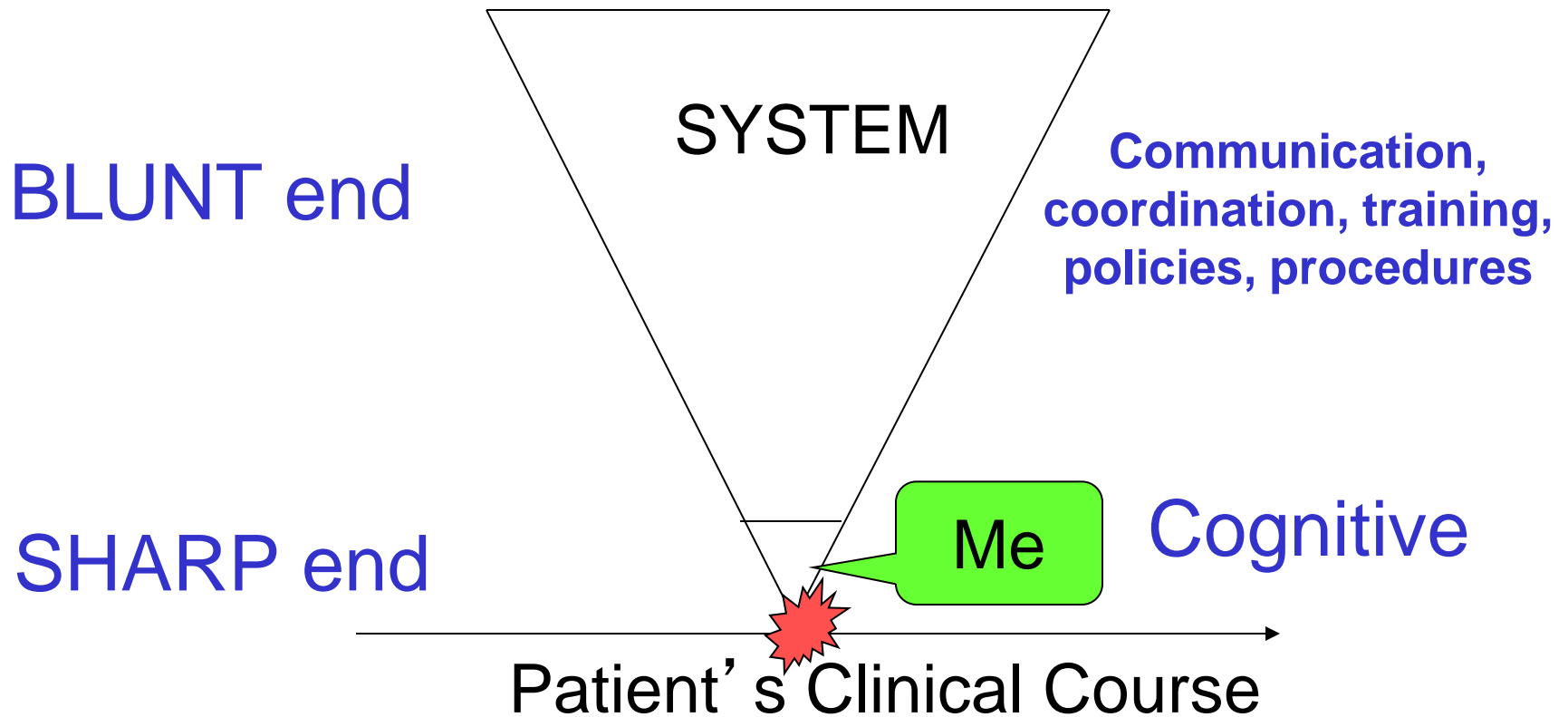
- **Survey of 262 internists**
- **They reported spending 74 minutes/day managing test results**
- **83% reported at least one unacceptable delay during the previous 2 months**

# **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





# Missed Diagnosis of Wegener's

## Cognitive Errors

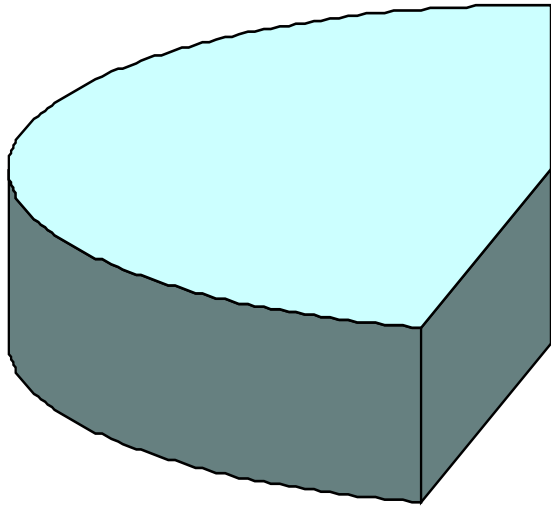
- **Knowledge:** OK
- **Data collection:** Faulty
- **Synthesis:** Context error & Premature closure

## 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.

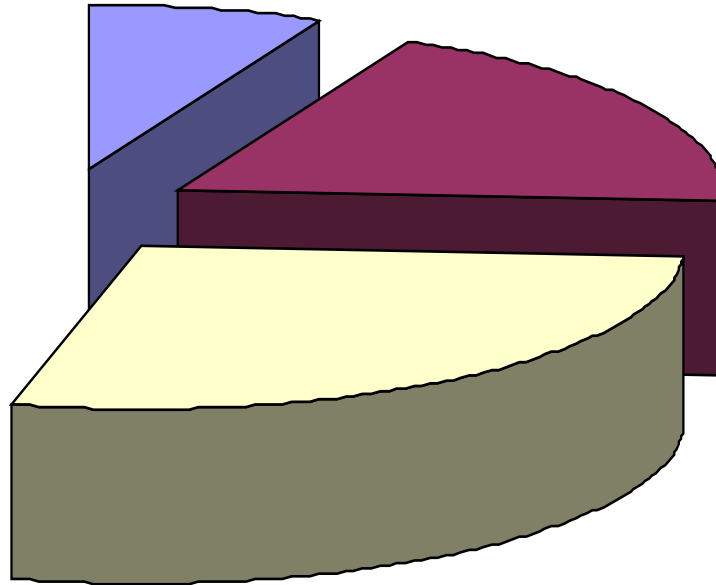
# Etiology of Diagnostic Error

**Both System and  
Cognitive Errors**  
46%



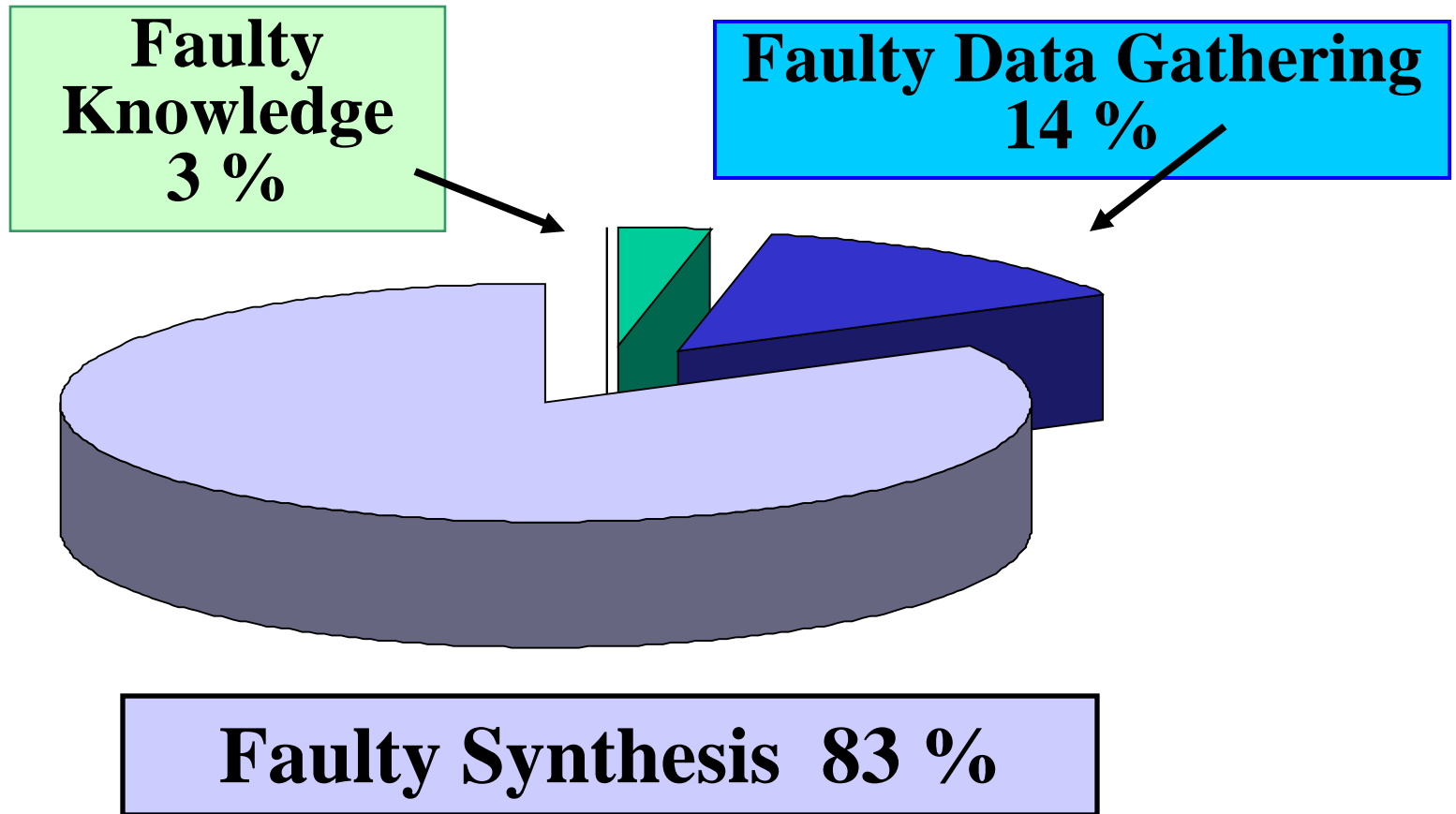
**No Fault Error Only**  
7%

**System Error Only**  
19%



**Cognitive Error Only**  
28%

# Cognitive Errors: 320



# Diagnostic Error – System Factors

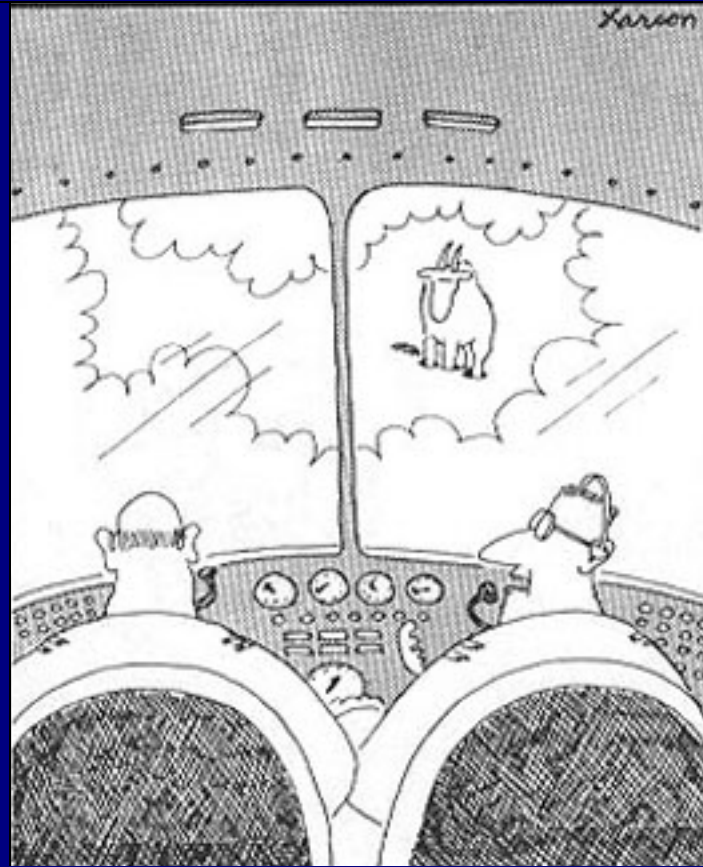
**215 system factors in the 100 cases**

- **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)**



*Mark Parisi*





**"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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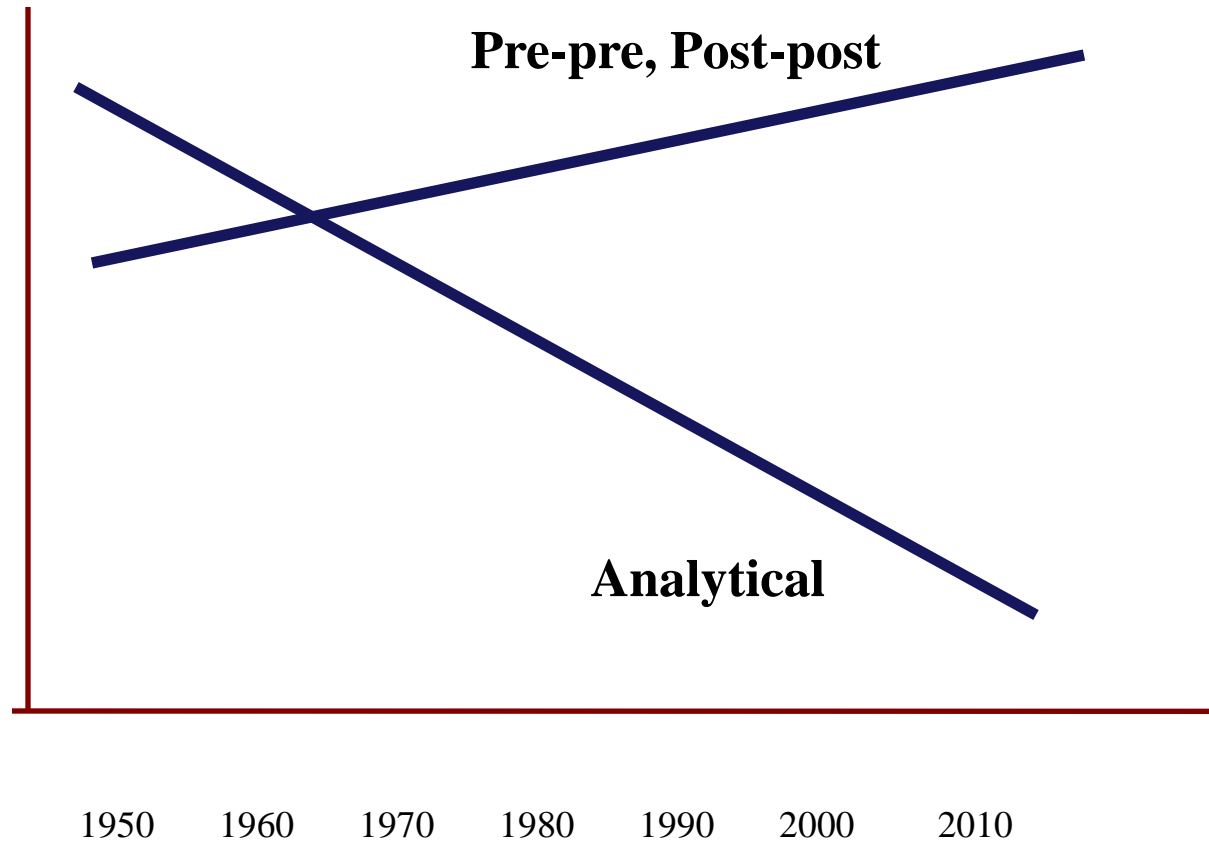
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## **Bad News**

- **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



# 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

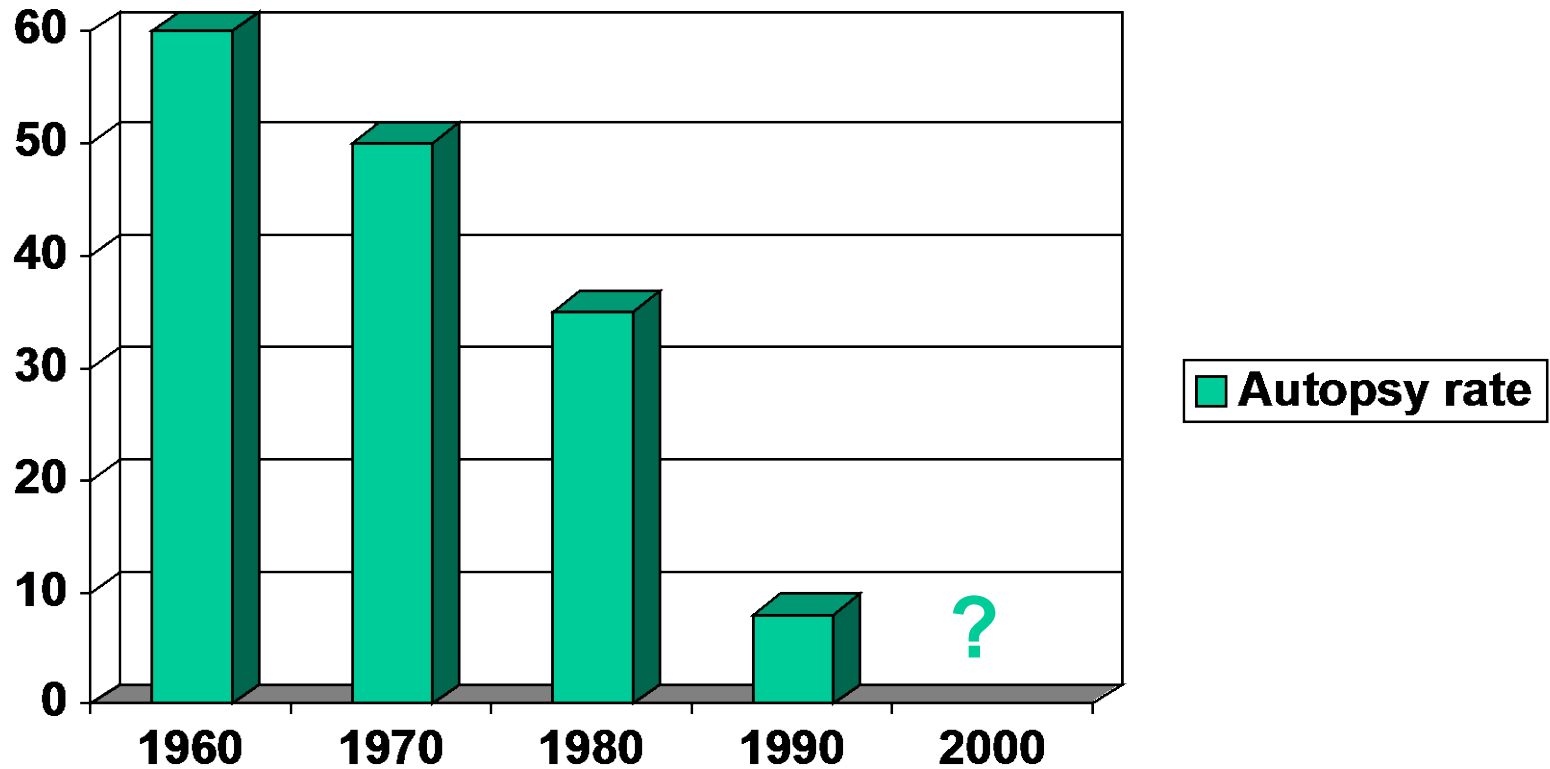
Simplify test ordering  
Use order sets

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?**

 Best Doctors

**WHEN YOU NEED TO BE SURE,  
CALL BEST DOCTORS.**

# **Geller et al. Second opinion in breast pathology**

J Clin Pathol 2014; 67: 955-960

## **Survey of 252 pathologists**

- 81% obtain second opinions (tho policies vary)**
- 96%: Improve accuracy and protect against malpractice suits**
- 66%: Easy to obtain**
- 85%: Did not take too much time**



# Swapp et al. Outside case review of surgical pathology for referred patients.

Arch Pathol Lab Med. 2013;137:233–240

## 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**

# **Park et al. Second opinion in thyroid fine needle aspiration biopsy by the Bethesda System**

Endocrine Journal 2012; 59: 205-212

## **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



Association of Directors of  
Anatomic and Surgical Pathology



**CAP/ADASP:  
Interpretive Diagnostic Error Reduction Project**

**Raouf Nakhleh, MD, CAP co-chair**

**Vania Nosé, MD, PhD, ADASP co-chair**

# Purpose

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- 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

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- 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

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- **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

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- **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





**SAVE THE DATE**

**2015**

**DIAGNOSTIC ERROR IN MEDICINE  
8TH INTERNATIONAL CONFERENCE**

27-29 SEPTEMBER, 2015 | WASHINGTON, D.C.