AN OVERVIEW OF DIAGNOSTIC ERROR IN MEDICINE
DISCLOSURES

- Society to Improve Diagnosis in Medicine – Director, Conference Chair, “EVP”
- Clinical Laboratory Management Association – President, Director
- Silicon BioDevices – Advisory Board, consultant
- SA Ignite - Investor
- Abbott Laboratories – retired, employee stock options
AGENDA

- Definitions
- Incidence
- Economics
- Measurement
- Causes
- Summary of unmet needs
DEFINITIONS

- missed, wrong, or delayed, as detected by some subsequent definitive test or finding.¹

- Any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis²

- missed opportunities in diagnosis³

Diagnostic Errors Model Revised

- Adverse Outcomes
- Diagnostic Process Failures
- Wrong/Delayed Diagnoses

Schiff, G. (2013 Sep), What’s in a Name, *Diagnostic Error in Medicine*, Chicago, Il.
KEY QUESTIONS REMAIN

- Can a diagnosis be wrong without a diagnostic error, e.g. no-fault?
- Can a diagnostic error occur if a condition is pre-emergent, i.e. asymptomatic?
- When does “time to diagnose” become a diagnostic error?
- Would diagnosis failure be more blame-free than error?
- Does missed diagnosis equal delayed diagnosis?
- What is Overdiagnosis? Is it misdiagnosis or misinterpretation?
Body of literature pointed to an incidence of 10-15% of diagnostic encounters\(^1\)

40,500 adult patients die annually with ICU misdiagnosis\(^2\)

5% of US adults experience diagnostic error annually in outpatient settings\(^3\)

More than one-half (54%) of pediatricians in a survey reported that they made a diagnostic error at least once or twice per month; almost one-half (45%) reported diagnostic errors that harmed patients at least once or twice per year.\(^4\)


## RESEARCH APPROACHES TO INCIDENCE

<table>
<thead>
<tr>
<th>Research approach</th>
<th>Findings—examples</th>
<th>Suitable for evaluating incidence</th>
<th>Suitable for evaluating aetiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autopsies</td>
<td>Major unexpected discrepancies that would have changed the management are found in 10–20% (^8) (^9)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Patient and provider surveys</td>
<td>One-third of patients relate a diagnostic error that affected themselves, a family member, or close friend (^10); Over half the surveyed paediatricians report making a diagnostic error at least once or twice a month (^11)</td>
<td>Limited</td>
<td>Limited</td>
</tr>
<tr>
<td>Standardised patients</td>
<td>Internists misdiagnosed 13% of patients presenting with common conditions to clinic (COPD, RA, others) (^12)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Second reviews</td>
<td>10–30% of breast cancers are missed on mammography (^13); 1–2% of cancers are misread on biopsy samples (^14)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Diagnostic testing audits</td>
<td>Errors related to laboratory testing are the most common reason for a diagnostic error (^15) (^16)</td>
<td>Very limited</td>
<td>Limited</td>
</tr>
<tr>
<td>Malpractice claims</td>
<td>Problems relating to diagnostic error are the leading cause for paid malpractice suits in every large system</td>
<td>Very limited</td>
<td>Limited</td>
</tr>
<tr>
<td>Case reviews (cross-sectional studies by symptom, disease, or condition); (may be enriched by trigger tools)</td>
<td>Patients with asthma—median delay in making the correct diagnosis was 3 years, or 7 visits (^17); 12–51% of patients with subarachnoid haemorrhage are misdiagnosed in the emergency department (^18) Of 1000 hospital deaths, 5% were considered preventable, and the most frequent aetiology was diagnostic error (^19)</td>
<td>Yes</td>
<td>Limited</td>
</tr>
<tr>
<td>Voluntary reports</td>
<td>1674 reports of diagnostic error were submitted to the UK’s National Reporting and Learning System over a 2-year period, 0.5% of all incidents reported (^20)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

COPD, chronic obstructive pulmonary disease; RA, rheumatoid arthritis.

The costs of diagnostic error have not been determined, but are associated with unnecessary office and hospital visits, wrong treatments, unnecessary tests and procedures, readmissions and deteriorating health status.

In a recent review\(^1\) of 25 years of malpractice claims, diagnostic errors were

- Leading type (28.6%) 
- Highest proportion of total payments (35.2%) 
- More often resulted in death than other allegation groups (40.9% vs 23.9%). 
- More outpatient than inpatient (68.8% vs 31.2%) 
- Responsible for payments of US$38.8 billion (inflation-adjusted)

Without a standard definition, measurement is more difficult.

Researchers have used triggers to increase the likelihood of detecting diagnostic error with mixed results still requiring manual chart review.

Sensitivity and specificity of most research efforts have been low, but could be sufficient for quality improvement although not for financial incentives.

We know of no effort initiated in any health system to routinely and effectively assess diagnostic performance.
# DIAGNOSTIC ERROR MEASURES WORKSHEET

<table>
<thead>
<tr>
<th>Measures</th>
<th>TIME PERIOD A</th>
<th>TIME PERIOD B</th>
<th>TIME PERIOD C</th>
</tr>
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<tbody>
<tr>
<td><strong>Outcome Measures</strong></td>
<td></td>
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<tr>
<td>a. Number of times an autopsy reveals a different definitive diagnosis / total number of autopsies performed</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
<tr>
<td>b. Number of times a postmortem MRI reveals a different definitive diagnosis / total number of postmortem MRIs performed</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
<tr>
<td>c. Number of patients with different admitting and discharge diagnoses / total number of patient discharges</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
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<tr>
<td><strong>Process Measures</strong></td>
<td></td>
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<tr>
<td><strong>Cognitive Processing</strong></td>
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<tr>
<td>a. Number of referrals with different or added diagnoses / total number of referrals in a specific patient population</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
<tr>
<td>b. Number of patients returned to the ED within 48 hours who are assigned a new or different diagnosis / total number of patient returns to the ED within 48 hours</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
<tr>
<td><strong>Testing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Number of pathology overreads / total number pathology specimens processed</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
<tr>
<td>b. Number of laboratory tests credited / total number of laboratory tests ordered</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
<tr>
<td>c. Number of radiology overreads / total number of radiology tests ordered</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
<tr>
<td><strong>Communication and Handoffs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Number of delays (specify timely consult) in obtaining consultations or referrals / total number of referrals/consults ordered within a specific patient population</td>
<td>0 / 0</td>
<td>0 / 0</td>
<td>0 / 0</td>
</tr>
</tbody>
</table>

Diagnosis Detection: Repeat Serum Creatinine Results (2009-2011)

5,324 lab orders placed for patients with an abnormal creatinine not repeated within 90 days

2,565 total labs repeated within 90 days (48%)

1,311 abnormal results (51%)

1,078 New CKDs identified

Kanter – 2012 – “Reducing Diagnostic Errors By Closing The Loop On Outpatient Care”
Cognitive error plays a role in the majority of diagnostic errors, yet
- Few medical schools or residencies have explicit curricula in clinical reasoning
- Few faculty are equipped to teach about cognitive psychology, informatics and clinical reasoning
- Few physicians receive feedback on their diagnostic performance

In addition to clinical reasoning, reduction in skill development is reported
- History & Physical\(^1\)
- Test ordering – radiology, laboratory
- Test result interpretation

LIMITED TRAINING TIME AND ACCELERATING TECHNOLOGY OPTIONS CREATE CHALLENGES

- Medical school education
  - Number of hours spent by medical students learning anatomic pathology: 61–302\(^1\) (range)
  - Median number of hours spent by medical students learning laboratory medicine: 8\(^2\) (75% of schools reporting)

- Leads to uncertainty\(^3\)
  - Primary care clinicians report ordering diagnostic tests on 31.4% of patient encounters.
  - Ordering uncertainty was reported on 14.7% and interpretation uncertainty on 8.3% of these diagnostic visits

- Test ordering choices have grown to nearly 5000 with an ever increasing complexity e.g. genetic tests

\(^2\)Smith, B. et al (submitted) Medical Student Education in Laboratory Medicine in United States Medical Schools: A 2014 Status Report
\(^3\)Hickner, J., et al. (2014). Primary Care Physicians’ Challenges in Ordering Clinical Laboratory Tests and Interpreting Results. The Journal of the American Board of Family Medicine, 27(2), 268–274.
A RECENT STUDY QUANTIFIES THE PROBLEM

- Overutilization is common (mean=20.6%) but varies systematically (n=118)
  - by clinical setting – initial (43.9%) vs. repeat (7.4%)
  - By test volume – low volume tests (32.2%) vs. high (10.2%)
  - measurement – restrictive (44.2%) vs. permissive (12.0%)
- Underutilization is also widespread, but understudied (mean=44.8%), (n=18)

Previous Tissue Diagnosis (pre 2002):
- Type of Cancer, size of Cancer, degree of spread

Evolution of the Tissue Diagnosis (post 2002, Personalized Medicine)
- Type of Cancer, size of Cancer, degree of spread
- Identification of molecular pathways utilized by the cancer to grow & spread supporting selection of targeted drugs that work on these specific pathways
- Molecular pathways utilized by the cancer to become resistant to the therapy supporting selection of targeted drugs to combat the pathways of resistance

Courtesy of Robert Penny, MD, PhD
# FIVE CAUSES TAXONOMY OF TESTING-RELATED DIAGNOSTIC ERROR (TDE)

<table>
<thead>
<tr>
<th>Cause</th>
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<tbody>
<tr>
<td>An inappropriate test is ordered</td>
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<tr>
<td>An appropriate test is not ordered</td>
</tr>
<tr>
<td>An appropriate test result is misapplied</td>
</tr>
<tr>
<td>An appropriate test is ordered, but a delay occurs somewhere in the total testing process</td>
</tr>
<tr>
<td>The result of an appropriately ordered test is inaccurate</td>
</tr>
</tbody>
</table>

Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Quality & Safety. 2013 August 16
NEW COLLABORATIVE ROLES ARE IMPERATIVE

- Most clinical laboratories do not have access to a clinical pathologist (reimbursement issues)
- Information systems tend to limit the laboratorian's access to patient context including findings, differential, other problems, medications (privacy, absence of perceived need drives EMR/LIS interface design)
- Scope of practice issues prevent laboratorians from modifying test orders or initiating new test orders unless included within an approve protocol
GAPS IN POLICY

- Recent legislative SGR-fix, which includes incentives linked to metrics, identified measurement gaps. Diagnostic error was not included as a measure or a gap.
- Structures of research organizations is not conducive to studying diagnosis, e.g., NIH is disease-oriented or population-based.
- Payers, through reliance on pay-for-performance, ignore diagnostic error as an opportunity to improve healthcare and reduce costs.
- National patient safety campaigns have ignored diagnostic error.
  - Joint Commission
  - National Quality Forum
  - Leapfrog Group
  - Agency for Healthcare Research and Quality

EHR documentation practices have largely been dictated by billing and legal requirements.¹

- AHRQ-funded a study (1R03HS022569) to define diagnostic pathways using the EMR and evaluate the potential to “crowd-source” best practices in diagnosis.
- EMR templates do not solicit a differential diagnosis or evidence of clinical reasoning; much of the data inserted into the record is not relevant to the current encounter and much of the data requested in the template supports billing.

HIT-related error occurs anytime HIT is unavailable for use, malfunctions during use, is used incorrectly by someone, or when HIT interacts with another system component incorrectly, resulting in data being lost or incorrectly entered, displayed, or transmitted.²

FAILURES IN DIAGNOSIS HAVE SIGNIFICANT CONSEQUENCES
SUMMARY OF UNMET NEEDS

- An operationally relevant definition for diagnostic error
- Practical strategies for monitoring performance as well as determining incidence
- Reexamination of roles in a collaborative team
- Shift in EMR development priorities to strengthen clinical effectiveness capabilities
- Medical school and MoC focus on clinical reasoning and diagnostic performance
- Strategies and tactics to activate broad stakeholder community
- Most importantly, determination of the priority of diagnostic error within the overall patient safety and healthcare reform ecosystem
Merging Policy, Practice and Technology: Paths to Improve Diagnosis

Diagnostic error is the leading cause of medical malpractice in the U.S. and patient harm globally, but is underemphasized and understudied. The Diagnostic Error in Medicine Conference is the premier event for medical professionals and patients with specific interest in improving the quality of medical diagnosis. Plan to join colleagues from all facets of healthcare for this thought-provoking and highly interactive program.

KEYNOTE PRESENTERS

Monday 15 September | Lucian Leape, MD

Lucian Leape, MD is widely regarded as the inspirational leader of the patient safety movement, beginning with his 1994 paper, Error in Medicine, which called for the application of industrial systems theory to prevent medical errors. He has authored over 150 journal articles and monographs on patient safety. He is currently Adjunct Professor of Health Policy at the Harvard School of Public Health and Chair of the Lucian Leape Institute.

Tuesday 16 September | Robert A Berenson, MD, FACP

Robert A. Berenson, MD, FACP, is a Senior Fellow at the Urban Institute and adjunct professor in the School of Public Health, the George Washington University School of Medicine, and the Fuqua School of Business at Duke University. Dr. Berenson is a board-certified internist who practiced for more than 20 years and has served on numerous medical panels and committees.

Wednesday 17 September | Otis Webb Brawley, MD, FACP

As the chief medical and scientific officer and executive vice president of the American Cancer Society, Otis Webb Brawley, MD, FACP is responsible for promoting the goals of cancer prevention, early detection, and quality treatment through cancer research and education. Dr. Brawley currently serves as professor of hematology, oncology, medicine and epidemiology at Emory University. He is also a medical consultant to the Cable News Network (CNN).

Registration and programming details will be announced in spring 2014. Visit www.DEM2014.org to learn more.
ACKNOWLEDGEMENTS

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- Hardeep Singh MD, MPH
- Julie Taylor, PhD
- Robert Trowbridge MD
QUESTIONS?