The National Academy of Medicine Report on Diagnostic Errors: Implications for Laboratory Practice

Michael Laposata, MD, PhD
Professor and Chairman
Department of Pathology
University of Texas Medical Branch
Galveston, TX
I have no conflicts of interest.
This presentation is a summary of the Institute of Medicine Committee on Diagnostic Error AND It is my personal summary of the number of errors experienced by Americans today
Methods of the Study

The Committee deliberated during five in-person meetings and numerous conference calls between April 2014 and April 2015. At three of the meetings, the Committee invited a number of speakers to inform its deliberations.
Origin of Task and Committee Charge

The IOM appointed an independent committee with a broad range of expertise, including:

Diagnostic error, patient safety, health care quality and measurement, patient engagement, health policy, health care professional education, cognitive psychology, health disparities, human factors and ergonomics, health information technology (health IT), decision analysis, nursing, radiology, pathology, law, and health economics.
Outline of the Presentation

1. Medical error
2. Diagnostic error
3. Why medical errors have been overlooked
4. What is broken and what are the fixes
5. The percentage of Americans experiencing diagnostic error
6. Perspectives
Medical Error

Includes All Medical Mistakes: Treatment and Diagnostic
<table>
<thead>
<tr>
<th>Cause</th>
<th>Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td>611,105</td>
</tr>
<tr>
<td>Cancer</td>
<td>584,881</td>
</tr>
<tr>
<td>Medical error</td>
<td>251,454*</td>
</tr>
<tr>
<td>COPD</td>
<td>149,205</td>
</tr>
<tr>
<td>Unintentional injuries</td>
<td>130,557</td>
</tr>
<tr>
<td>Stroke</td>
<td>128,978</td>
</tr>
<tr>
<td>Alzheimer’s disease</td>
<td>84,767</td>
</tr>
<tr>
<td>Diabetes</td>
<td>75,578</td>
</tr>
<tr>
<td>Influenza and pneumonia</td>
<td>56,979</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>47,112</td>
</tr>
<tr>
<td>Suicide</td>
<td>41,149</td>
</tr>
</tbody>
</table>

*Authors’ calculation

A new study estimates that **medical error** was the cause of 251,454 deaths in 2013, making it the third-most common cause of death in the U.S.

Sources: Centers for Disease Control and Prevention; BMJ Publishing group Ltd.

@sdutgraphics
ICD-10 Coding System Cannot Capture Medical Errors

<table>
<thead>
<tr>
<th>Condition</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction</td>
<td>X</td>
</tr>
<tr>
<td>Stroke</td>
<td>X</td>
</tr>
<tr>
<td>Cancer</td>
<td>X</td>
</tr>
<tr>
<td>Diabetes</td>
<td>X</td>
</tr>
</tbody>
</table>

No code for an ADMISSION or READMISSION following a missed or delayed diagnosis!
There have been at least three studies providing estimates of the number of deaths associated with medical error:

80,000 to 160,000 per year
*BMJ Qual Saf 22:672, 2013*

400,000 per year
*J Patient Saf 9:122-128, 2013*

251,000 per year in 2013
*BMJ 353:i2139, 2016*
Taking an average of these, there are 257,000 deaths per year contributed to medical error with 25 percent as diagnostic error-related deaths.
There are an estimated 64,000 deaths annually due to diagnostic error.
# Wars Ranked by US Combat Deaths

<table>
<thead>
<tr>
<th>Rank</th>
<th>War</th>
<th>Years</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>World War II</td>
<td>1941–1945</td>
<td>291,557</td>
</tr>
<tr>
<td>2</td>
<td>American Civil War</td>
<td>1861–1865</td>
<td>212,938</td>
</tr>
<tr>
<td>3</td>
<td>World War I</td>
<td>1917–1918</td>
<td>53,402</td>
</tr>
<tr>
<td>4</td>
<td>Vietnam War</td>
<td>1955–1975</td>
<td>47,424</td>
</tr>
<tr>
<td>5</td>
<td>Korean War</td>
<td>1950–1953</td>
<td>33,746</td>
</tr>
<tr>
<td>6</td>
<td>American Revolutionary War</td>
<td>1775–1783</td>
<td>8,000</td>
</tr>
<tr>
<td>7</td>
<td>War on Terror</td>
<td>2001–present</td>
<td>5,281</td>
</tr>
<tr>
<td>8</td>
<td>War of 1812</td>
<td>1812–1815</td>
<td>2,260</td>
</tr>
<tr>
<td>9</td>
<td>Mexican-American War</td>
<td>1846–1848</td>
<td>1,733</td>
</tr>
<tr>
<td>10</td>
<td>Northwest Indian War</td>
<td>1785–1795</td>
<td>1,221+</td>
</tr>
<tr>
<td>11</td>
<td>Kosovo</td>
<td>1999–2014</td>
<td>18+</td>
</tr>
</tbody>
</table>

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Diagnostic Error

A Subset of Medical Errors
The Committee developed a patient-centered definition of diagnostic error:

The failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient.
Diagnostic Error: An error that occurs in any one of the steps shown in this diagram.
The Most Common Misdiagnoses Involve Frequently Encountered Disorders – and These Misdiagnoses Can Occur from Underutilization of Lab Tests

<table>
<thead>
<tr>
<th>Adults:</th>
<th>Lung Cancer</th>
<th>Acute MI</th>
<th>Colorectal Cancer</th>
<th>Pulmonary Embolism</th>
<th>Acute Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Children:</th>
<th>Meningitis</th>
<th>Pneumonia</th>
<th>Malignant Tumor</th>
<th>Benign Tumor</th>
<th>Appendicitis</th>
</tr>
</thead>
<tbody>
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<td>Meningitis</td>
<td>Pneumonia</td>
<td>Malignant Tumor</td>
<td>Benign Tumor</td>
<td>Appendicitis</td>
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Diagnostic Error as Percentage of Medical Error

- Diagnostic Error
- Mild
- Severe
- Moderate

1/4
1/4
1/2
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1950

Amount of knowledge available about disease

Doctor does not know much about diagnosis

Doctor knows much about diagnosis
Today

Amount of knowledge available about disease

Less Informed Doctor

More Informed Doctor
The Complication from a Diagnostic Error May Appear Months-to-Years After the Mistake Has Been Made

During the period of 1981 to 1984:

- An ear, nose, and throat surgeon is faced with an eight year old boy requiring a tonsillectomy

- The boy has a PTT that is elevated

- Without knowing that the boy has a deficiency in a coagulation factor (XII) that is not predisposed to bleeding, the surgeon orders fresh frozen plasma

- One out of 20 bags of fresh frozen plasma contains active hepatitis C virus or HIV
The Complication from a Diagnostic Error May Appear Months-to-Years After the Mistake Has Been Made

What is the likelihood that the ENT surgeon’s diagnostic error years earlier regarding the prolonged PTT is perceived as the cause of these dreaded infections?

This is highly unlikely to be counted as a diagnostic error.
The Most Dangerous Scenario of All:

When Doctors “Don’t Know What They Don’t Know”

But They Actually Think They Do Know It
Patient is 22 years old and claims to be pregnant because she has missed a period. She presents with abdominal pain and needs an imaging study.

The imaging study should not be performed if the patient is pregnant as the radiation can be harmful to a fetus.
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What is Broken

and What Can be Done
to Fix It
What is Broken?

Failure to build diagnostic teams of health professionals
The Diagnostic Management Team Provides Advice on the Appropriate Laboratory Tests to Select and the Interpretation of Complex Clinical Laboratory Evaluations
Conventional Approach

Isolated Diagnostic Bits of Data - Assembly by Ordering Physician Minimally Trained in Test Selection and Interpretation
Diagnostic Management Team Approach

Ordering Doctors

Solved Diagnostic Puzzle

Lab Directors

There Is No Wall between the Ordering Doctors and the Diagnostic Doctors

Receives Accurate Diagnosis Quickly as a Completed Puzzle
Data Presentation in the Medical Record for Coagulation Studies Prior to Initiation of the Patient-specific, Expert-driven Coagulation Interpretation
June 30, 2010

Pat-PT: 13.9  PT-inr: 1.1  PTT-pt: 43.6*
PoolNP: 28.1  P+N0Hr: 38.3
P+N1Hr: 36.2  P+N2Hr: 35.9
Pat-TT: 15  F8Act: 95
F9Act: 102  RVVT: 1.5*
DRVVT: Lupus
Anticoagulant Confirmed  DMX: 1.3
F11Act: 96  F12Act: 54
Report in the Medical Record After Initiation of the Daily Rounds to Interpret All Complex Evaluations from the Special Coagulation Laboratory
This patient has an elevated PTT, with a normal PT/INR and normal thrombin time.

A PTT mixing study failed to correct into the normal range. These results were consistent with the presence of an inhibitor (such as a lupus anticoagulant) in the sample.

The Dilute Russell Viper Venom time (dRVVT) is used for detection of Lupus Anticoagulant, and the test was positive, indicating the presence of Lupus Anticoagulant.

Taken together, this is a patient with a prolonged PTT based upon the presence of a lupus anticoagulant. There is no increased bleeding risk in this patient, despite the prolonged PTT.
Comparison of Length of Stay and Total Charges Pre and Post Aug 1, 2010

Percent of Cases with LOS greater or equal to 4 days:
- Jan - Jul (Before): 36.75%
- Aug - Dec (After): 12.50%

Chi-sq significant at .05

Bottom Line:
It appears that the changes in the median LOS are due to truncation of the right tail.

Aquino, AC. How to spot the savings from a diagnostic team. CAP Today, October 2017
MSDRG 65: Intracranial Hemorrhage

Comparison of Length of Stay and Total Charges Pre and Post Aug 1, 2010

Percent of Cases with LOS greater or equal to 10 days
- Jan - Jul (Before) 14.5%
- Aug - Dec (After) 2.25%
- Chi-sq significant at .05.

Bottom line: It appears that the changes in median LOS are due to truncation of the right tail.

Aquino, AC. How to spot the savings from a diagnostic team. CAP Today, October 2017
The Fix

Remove the barriers to the creation of diagnostic management teams and pay for the interpretation of laboratory test results similar to payment for anatomic pathology and radiology.
What is Broken?

Failure to involve the patient

The visits are too short – most doctors do not have time to clearly explain to patients what they have and what to do if they do not recover

And many doctors do not have enough information to explain what the patient actually has – factor V Leiden?
The Fix

A new system needs to be put into place that allows more time for discussion between the patient and the physician - And the willingness of the physician, when necessary, to have an expert describe a patient’s condition
What is Broken?

Failure to optimize health information technology

There is so much more to do than what we are currently doing that would significantly benefit patient outcome and healthcare expenditures
A lab system addresses what is circled in green.

To make a major reduction in medical error, it must also address what is circled in red.

The nine steps in the performance of any laboratory Test. The brain-to-brain turnaround time loop.

The Fix

For the information systems company with adequate resources and a vision for the future –

The principle need is to bring an expert to every healthcare provider who needs help in diagnostic test selection and result interpretation.
What is Broken?

Failure to provide payment for individuals in the healthcare system providing advice on the selection and result interpretation for diagnostic tests
The Fix

Pay pathologists and clinical laboratory scientists not only for anatomic pathology services but also for consultation on laboratory test selection and result interpretation,

and incentivize them to build expert diagnostic management teams, particularly in academic medical centers where a larger number of pathologists are employed
What is Broken?

Failure to recognize the impact of diagnostic error, both immediate and long-term by Physician and non-physician healthcare institution leaders
Improvement in Clinical Services:
Who is the Expert Who Leads the Improvement?
What is the Role of the Non-expert?
The Fix

Build a strong partnership between administrators with financial and operational expertise and medical doctors to make decisions with the most information possible –

So cost savings alone are not the driving force and inefficient clinical practices do not prevail
What is Broken?

Within the health system, failure to share information on diagnostic errors between patients and families due to legal barriers
Why Doctors Do Not Want to Tell a Patient About Diagnostic Errors and Imply that Their Own Errors were Caused by Someone Else

- It is embarrassing
- It induces a lack of confidence in the doctor
- It may lead to legal action by the patient against the doctor
Why Doctors Do Not Want to Tell a Patient About Diagnostic Errors and Imply that Their Own Errors were Caused by Someone Else

• It may lead to a reduction of patients in a practice and loss of income

• Blame is easily passed on to persons/services not present in the room (“The lab did not do the correct tests” is really “I didn’t know which tests to order and selected the wrong ones”)
The Fix

Doctors must avoid all misrepresentation about medical errors, large and small –

There must be a willingness to admit that a diagnostic evaluation was incomplete, or overdone, and that a misdiagnosis was not someone else’s fault
What is Broken?

Failure to educate medical students on appropriate use of diagnostic tests and when to refer test selection and result interpretation to an expert.
Survey of US Medical Schools
Brian Smith and the CLIHC™ Group at the CDC

Number of hours spent by medical students learning anatomic pathology: 61 – 302 is the range

Median number of hours spent by medical students learning laboratory medicine: 8 hours of lecture

And there is most often no test for the laboratory medicine coursework, and the teaching is often done by individuals with no laboratory medicine training

An Educational Mismatch with Medical Practice Competency Which has Long Needed Correction

What medical students are taught about the diagnostic tests they will use in practice?

- Anatomic pathology tests
- Radiology tests
- Clinical laboratory tests

What diagnostic tests do doctors order in practice and are required to interpret the test results by themselves?

- Anatomic pathology tests
- Radiology tests
- Clinical laboratory tests
The Fix

A required course for medical students in the United States to teach the appropriate selection of diagnostic tests and interpretation of test results must be initiated.

There must be an appropriate number of questions on the licensing board exam on this topic.
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The Percentage of Americans Experiencing Diagnostic Error
Percentage of Adult Americans Experiencing Diagnostic Error

>99%
How Big is the Problem of Diagnostic Error?

Post-IOM Report, 2015: Most adult Americans have experienced a diagnostic error

Today - This Presentation Personal Data Review: How many diagnostic errors per person in a lifetime? 1? 10? 50?
The Average of the Results for These Six Disease-based Diagnostic Errors

55%  Pulmonary embolism
30%  Subarachnoid hemorrhage
44%  Cancer
21%  Breast cancer
69%  Bipolar disease
18%  Diabetes

An average of **39.5%** diagnostic error for the six disease-based examples
Diagnostic Errors Associated with Office Visits and Initial In-patient Visits

Study A
(a summary of six studies involving six different disorders)

39.5% of cases

www.alternet.org/story/88515/the_startlingtruth_aboutdoctorsanddiagnosticerrors

Study B
(Focused on laboratory test ordering mistakes)

11.5%

(J Am Board Fam Med 27:268-274, 2014)
## Diagnostic Errors Associated with Office Visits and Initial In-patient Visits

<table>
<thead>
<tr>
<th>Study C</th>
<th>5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>(with the authors indicating that this is likely a significant underestimation)</td>
<td>(BMJ Qual Saf 23:1023-1030, 2014)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study D</th>
<th>6.6% Medical – 1.45% Diagnostic error</th>
</tr>
</thead>
<tbody>
<tr>
<td>(considers medical errors of all types – diagnostic errors would be about 25% of this total)</td>
<td>(J Med Econ 16:1367-1378, 2013)</td>
</tr>
</tbody>
</table>
Diagnostic Errors Associated with Office Visits and Initial In-patient Visits

This averages to 14.3% of the office and in-patient visits involving a diagnostic evaluation are associated with a diagnostic mistake.

This averages to 1 in 7 outpatient/in-patient encounters requiring a diagnosis involves an error in diagnosis.
How Many Medical Errors, Including Diagnostic Errors, Should You Expect to Experience Yourself?

Number of visits to a doctor (outpatient and inpatient):
- Age 0-5: 3/year = 15
- Age 5-65: 2/year = 120
- Age 65-90: 4/year = 100

325

Assume only half of these are associated with possible new diagnoses:

160 diagnostic visits

Assume error in one out of 10 visits (<1 out of 7):

16 errors in a lifetime FOR ONE PERSON
Percentage of Adult Americans Who Think They Have Experienced Diagnostic Errors

Only 20% or one out of five people
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Perspectives
Patients Cannot Effectively Assess the Skill Level of Doctor

<table>
<thead>
<tr>
<th>Bedside Manner</th>
<th>Skill Level</th>
<th>Perception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polite and kind</td>
<td>Highly competent</td>
<td>“Good Doctor”</td>
</tr>
<tr>
<td>Polite and kind</td>
<td>Incompetent</td>
<td>“Good Doctor”</td>
</tr>
<tr>
<td>Dr. “HODAD”:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hands of Death</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and Destruction</td>
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<td></td>
</tr>
</tbody>
</table>
Medical Errors
I Have Personally Experienced

SEVERE, DIAGNOSTIC: Major blow to the head, unconscious for 10 minutes; primary care physician took my blood pressure and sent me home with no observation period.

MINOR, TREATMENT: Prescribed a bowel stimulant for an upper respiratory tract infection.

MODERATE, DIAGNOSTIC: Underwent an esophageal biopsy which was lost before it could be reviewed by pathology.
Medical Errors
I Have Personally Experienced

MINOR, DIAGNOSTIC: Esophageal biopsy result received 13 days after completion of the biopsy

MODERATE, DIAGNOSTIC: CAT scan for pulmonary embolus (70 times the radiation of a chest x-ray) when I was not short of breath and only because I had been on an airplane

MODERATE, TREATMENT: Virtually no advice on cardiovascular protection using aspirin or fish oil
Medical Errors
I Have Personally Experienced

MODERATE, DIAGNOSTIC: Gum infection following dental implant of a molar with delay in recognition of the infection and loss of the implant.

MODERATE, DIAGNOSTIC: Inadequate bowel preparation dose prior to lower G.I. evaluation making the evaluation for cancer in the large intestine impossible.

There are 2 additional treatment errors not mentioned on these slides.
Number of Diagnostic Errors in One ICU Stay Can Be Many Because There Are Many Diagnoses to Be Made or Ruled Out in One Stay

Primary clinical problem is diagnosed

Change in primary problem must be monitored and appearance of new problems detected

Diagnosis of complications must be rapid and accurate for:

- MI
- Stroke
- DVT/PE
- CLABSI
- UTI
- VAP
- Respiratory compromise
Goals for Improving Diagnosis and Reducing Diagnostic Error

- Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families
- Enhance health care professional education and training in the diagnostic process
Goals for Improving Diagnosis and Reducing Diagnostic Error

- Ensure that health information technologies support patients and health care professionals in the diagnostic process.

- Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice.
Goals for Improving Diagnosis and Reducing Diagnostic Error

- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance

- Develop a reporting environment and medical liability system that facilitates improved diagnosis through learning from diagnostic errors and near misses
Goals for Improving Diagnosis and Reducing Diagnostic Error

- Design a payment and care delivery environment that supports the diagnostic process
- Provide dedicated funding for research on the diagnostic process and diagnostic errors