IMPROVING DIAGNOSIS IN HEALTH CARE: A GRAND CHALLENGE & OPPORTUNITY FOR INFORMATICS

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Baylor College of Medicine
Most Americans will get a wrong or late diagnosis at least once in their lives

By Lena H. Sun  September 22

Most Americans who go to the doctor will get a diagnosis that is wrong or late at least once in their lives, sometimes with terrible consequences, according to a report released Tuesday by an independent panel of medical experts.

This critical type of health-care error is far more common than medication mistakes or surgery on the wrong patient or body part. But until now, diagnostic errors have been a relatively understudied and unmeasured area of patient safety. Much of patient safety is focused on errors in hospitals, not mistakes in diagnoses that take place in doctors’ offices, surgical centers and other outpatient facilities.

The new report by the Institute of Medicine, the health arm of the National Academy of Sciences, outlines a system-wide problem. The report's authors say they don't know how many diagnostic errors take place. But the report cited one estimate that such errors affect at least 12 million adults each year, or about 5 percent of adults who seek outpatient care.
Objectives

- Describe the burden of diagnostic errors in electronic health record-enabled healthcare settings

- Discuss types of patient safety concerns involving diagnosis that can occur in EHR-enabled health care

- Identify potential informatics solutions and conceptual frameworks for mitigating diagnostic safety risks in EHR-enabled health care
Poll Question #1: My main role in the VA is
__________________.

- Research Investigator/Research Staff
- Administrative/Operations
- IT/Informatics
- Clinician/Clinical Staff
- Other (specify)
Early Work

- Evaluated evidence of ‘errors’ in integrated system
- Detailed review of comprehensive EHR to evaluate diagnostic process in the patient’s journey across the continuum of care
  - Data available from primary care, specialty (secondary) care, ER, hospital, diagnostics (lab/imaging/pathology), procedures

Singh et al Arch Intern Med. 2007; Singh et al Arch Intern Med 2009
Common conditions missed in outpatient settings despite clear red-flags (5% or 1 in 20 US Adults/year)

About half had potential for clear harm

Singh et al JAMA IM 2012;
Singh et al BMJQS 2014
The Battle Against Misdiagnosis

American doctors make the wrong call more than 12 million times a year.

By HARDEEP SINGH

Aug. 7, 2014 7:16 p.m. ET

There are times when a single, unexpected death sparks a change in medical practice. In 2012 a 12-year-old boy named Rory Staunton died after being misdiagnosed in a New York City emergency room. Multiple physicians missed the symptoms, signs and lab results pointing to a streptococcal bacterial infection that led to septic shock and overwhelmed Rory's body. The tragedy introduced "Rory's rule," which requires doctors to re-check similar incidents in hospital journals.

Comparable initiatives are needed at the national level—but there might be other caveats.

New research my colleagues and I will soon publish in the Journal of Patient Safety shows the extent of the problem is likely higher than we previously believed, even among adult patients seeking outpatient care.

Misdiagnosed: Docs' Mistakes Affect 12 Million a Year

By JONEL ALECCIA

At least one in every 20 adults who seeks medical care in a U.S. emergency room or community health clinic may walk away with the wrong diagnosis, according to a new analysis that estimates that 12 million Americans a year could be affected by such errors.

Of those misdiagnosis mistakes, about 6 million could potentially cause harm, according to patient safety expert Dr. Hardeep Singh, who is the first to provide robust population-level data on the impact of the problem in outpatient settings.

That means patients with conditions as varied as heart failure, pneumonia, anemia and amputations have been harmed, underestimated or over-treated.
Safety Begins with Measurement

We cannot improve what we cannot measure!

We cannot measure what we cannot define!
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
What are Diagnostic Errors?

- Case analysis reveals evidence of a missed opportunity to make a correct or timely diagnosis.
- Missed opportunity is framed within the context of an “evolving” diagnostic process.
- The opportunity could be missed by the provider, care team, system, and/or patient.
Defining Preventable Diagnostic Harm

A. MISSED OPPORTUNITIES

B. HARM
(from delayed or wrong treatment/test)

C. NO MISSED OPPORTUNITIES

D. Missed opportunities in diagnosis due to system and/or cognitive factors

Preventable diagnostic harm

Delayed/wrong diagnosis associated with patient harm but no clear evidence of missed opportunities

Delayed/wrong diagnosis but no clear evidence of missed opportunities

Adapted from Singh Jt Comm J Qual Patient Saf 2014
What Types of Conditions Affected?

- **US**
  - Pediatrics survey: Viral illnesses diagnosed as bacterial, medication side effects, psychiatric disorders, and appendicitis
    
  - Adult primary care chart review study: Pneumonia, decompensated CHF, symptomatic anemia
    
  - Netherlands hospitals
    - Chart review study: PE, sepsis, MI, appendicitis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th># cases</th>
<th>%</th>
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<tbody>
<tr>
<td>Pulmonary embolism</td>
<td>26</td>
<td>4.5%</td>
</tr>
<tr>
<td>Poisoning, ADR, overdose</td>
<td>26</td>
<td>4.5%</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>23</td>
<td>3.9%</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>19</td>
<td>3.3%</td>
</tr>
<tr>
<td>Acute coronary syndrome</td>
<td>18</td>
<td>3.1%</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>18</td>
<td>3.1%</td>
</tr>
<tr>
<td>Stroke</td>
<td>15</td>
<td>2.6%</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>13</td>
<td>2.2%</td>
</tr>
<tr>
<td>Fracture</td>
<td>13</td>
<td>2.2%</td>
</tr>
<tr>
<td>Abscess</td>
<td>11</td>
<td>1.9%</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>10</td>
<td>1.7%</td>
</tr>
<tr>
<td>Aortic aneurysm/dissection</td>
<td>9</td>
<td>1.5%</td>
</tr>
<tr>
<td>Appendicitis</td>
<td>9</td>
<td>1.5%</td>
</tr>
<tr>
<td>Depression</td>
<td>9</td>
<td>1.5%</td>
</tr>
</tbody>
</table>
Contributing Factors

Overconfidence

Faulty synthesis

Faulty data gathering

Sample mix-up

Premature closure

Process failure

Unintended consequence of policy

Failure to detect physical finding

Affective bias

Perception error

Wrong estimate of pretest probability

Misinterpretation of test

Failure to follow-up abnormal test

Inadequate follow-up

Limited access

Communication failure

Failed heuristic

Language barrier

Faulty triggering

Knowledge deficit

Uninformed patient
Grand Challenges

- Common diseases missed despite red flags
  - Failure to elicit key history or exam finding
  - Overlooking critical information in EHRs
- Complex systems and cognitive issues involved
  - Not black and white
  - Under-diagnosis vs. over-zealous diagnostic pursuits
  - Chaotic clinical settings & inadequate time
- Lack of feedback systems for improvement

Meyer et al JAMA IM 2013; Singh et al JAMA IM 2013; Sarkar et al BMJQS 2012
Grand Challenges

- No magic bullet for improving cognition
- No single system fix
- Fine balance between system issues and personal responsibility and accountability
- How many diseases to focus on?
An Opportunity for Informatics

THE WORK SYSTEM
- Diagnostic Team Members
- Tasks
- Technologies and Tools
- Organization
- Physical Environment
- External Environment

THE DIAGNOSTIC PROCESS

Patient Experiences a Health Problem
Patient Engages with Health Care System
Information Gathering
Information Integration
Working Diagnosis
Communication of the Diagnosis
Treatment
Outcomes

Patient and System Outcomes
Learning from diagnostic errors, near misses, and accurate, timely diagnoses
Potential Areas of Informatics Solutions

- Information Technology
- Measurement
- Communication and Teamwork
- Patient Engagement
Our goals are to use health IT to measure and reduce diagnostic errors and harm, but ..

Current Reality: Trying to ensure health IT itself is being used ‘safely’
Communication of Test Results

- Evaluation of 1,163 outpatient abnormal lab & 1,196 abnormal imaging test result alerts
  - 7% abnormal labs lacked timely follow-up
  - 8% abnormal imaging lacked timely follow-up

- Why abnormal test results continue to get missed in health IT-based settings

Ambiguous Responsibility a Huge Issue
Too many electronic health record alerts may be leading doctors to skip them

Your doctor may be more likely to ignore your test results if they come electronically.

A new study published in the JAMA Internal Medicine on Mar. 4 revealed that doctors receive about 63 electronic health record (EHR)-based alerts each day, which are supposed to let them know about abnormal patient results. And, almost one-third of the doctors surveyed -- about 30 percent -- admitted that they had missed some results because of too many alerts.

"If you're getting 100 emails a day, you are bound to miss a few. I study this area and I still sometimes miss emails. We have good intentions, but sometimes getting too many can be a problem," Dr. Hardeep Singh, chief of health policy, quality, and informatics at the Michael E. DeBakey Veterans Affairs Medical Center, in Houston, told TIME.
And More Digital Data Is on the Way

- **Smartphone**

- **Wearables**

  "Patients can now continuously monitor their data real-time and send it to their docs"
## Multiple “Socio-Technical” Issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Software</strong></td>
<td>no functionality for saving, tracking, and retrieving alerts</td>
</tr>
<tr>
<td><strong>Content</strong></td>
<td>too many unnecessary alerts</td>
</tr>
<tr>
<td><strong>Usability</strong></td>
<td>poor signal to noise ratio on screen</td>
</tr>
<tr>
<td><strong>Workflow</strong></td>
<td>“surrogate feature” to forward alerts when providers out of office not used properly</td>
</tr>
<tr>
<td><strong>Providers</strong></td>
<td>lack of knowledge/training</td>
</tr>
<tr>
<td><strong>Organizational</strong></td>
<td>policies for follow-up ambiguous</td>
</tr>
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8-dimensional Socio-Technical Model of Safe & Effective Health IT Use
Health IT Safety Framework – 3 Domains

- Domain 1: Safe health IT:
  - Events unique/specific to health IT

Smokers prescribed Viagra to quit

Smokers trying to quit the habit were mistakenly prescribed anti-impotence drug Viagra by doctors.

NHS Greater Glasgow and Clyde said the error was due to a computer glitch at two city GP practices.

When GPs selected anti-smoking pill Zyban, computers selected sildenafil, the generic name for Viagra.

A health board spokeswoman said: "At no time was patient care affected by this as all prescriptions are subject to stringent double checking."

The e-Formulary computer system used by GPs automatically selects a list of the most popular drugs when doctors fill out prescriptions.

Some patients went to the pharmacy with a prescription for the anti-impotence drug instead of tablets to help them stop smoking.
Health IT Safety Framework— 3 Domains

- Domain 1: Safe health IT:
  - Events unique/specific to health IT

- Domain 2: Using health IT safely:
  - Unsafe or inappropriate use of technology
  - Unsafe changes in the workflows that emerge from technology use

Divvy K. Upadhyay, Dean F. Sittig and Hardeep Singh*

**Ebola US Patient Zero: lessons on misdiagnosis and effective use of electronic health records**

**Abstract:** On September 30th, 2014, the Centers for Disease Control and Prevention (CDC) confirmed the first travel-associated case of US Ebola in Dallas, TX. This case exposed two of the greatest concerns in patient safety in the US outpatient health care system: misdiagnosis and ineffective use of electronic health records (EHRs). The case received widespread media attention highlighting failures in disaster management, infectious disease control, national security, and emergency department (ED) care. In addition, an error in making a correct and timely Ebola diagnosis on initial ED presentation brought diagnostic decision-making vulnerabilities in the EHR era into non-technical factors will be needed. Ebola US Patient Zero reminds us that in certain cases, a single misdiagnosis can have widespread and costly implications for public health.

**Keywords:** cognition; decision-making; diagnostic error; Ebola; electronic medical records; health information technology; human factors; misdiagnosis; patient safety.

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Health IT Safety Framework – 3 Domains

- Domain 1: Safe health IT:
  - Events unique/specific to EHRs

- Domain 2: Using health IT safely:
  - Unsafe or inappropriate use of technology
  - Unsafe changes in the workflows that emerge from technology use

- Domain 3: Using health IT to improve safety
  - Leveraging health IT to identify unsafe care processes and potential patient safety concerns before harm

Development and Validation of Electronic Health Record–based Triggers to Detect Delays in Follow-up of Abnormal Lung Imaging Findings

Electronic health record-based triggers to detect potential delays in cancer diagnosis

Daniel R Murphy,1,2 Archana Laxmisan,1,2 Brian A Reis,1,2 Eric J Thomas,3 Adol Esquivel,4 Samuel N Forjuoh,5 Rohan Parikh,6 Myrna M Khan,1,2 Hardeep Singh1,2

ABSTRACT
Background Delayed diagnosis of cancer can...
Health Information Technology Safety Measurement Framework (HITS Framework)

Sociotechnical Work System* †

Health IT Safety Domains

Safe HIT
- Integrity
- Availability
- Confidentiality

Safe use of HIT
- Usability
- Complete Use
- Correct Use

Using HIT to improve safety
- Surveillance & Optimization

Italicized text denotes domain principles

Changes in standards, regulations, policy and practice

Retrospective & Prospective measurement through measures/eMeasures that are:

1. Important
2. Scientifically acceptable
3. Transparent
4. Feasible
5. Useable

Expected Measurement Impact
- Integration of HIT safety with existing clinical risk management & patient safety program
- Organizational learning
- Shared responsibility
- 360° assessment
- Refinement of measurement tools/strategies

Safer HIT-enabled healthcare

Feedback to EHR developers and health care organizations

Improved value of health care

Improved patient outcomes

* Includes 8 technological and non-technological dimensions.
† Includes external factors affecting measurement such as payment systems, legal factors, national quality measurement initiatives, accreditation, and other policy and regulatory requirements.
To Enable Rigorous Measurement

- Missed opportunity measurement must reflect real-world practice
  - more than just what’s in “the doctors head”
  - systems, team members, and patients, all inevitably influence clinicians’ thought processes

Singh BMJQS 2013
Safer Dx Framework for Measurement & Reduction

Sociotechnical Work System*

Diagnostic Process Dimensions

- Patient-provider encounter & initial diagnostic assessment
- Diagnostic test performance & interpretation
- Follow-up and tracking of diagnostic information
- Subspecialty consultation/referral issues

Measurement of diagnostic errors
- Reliable
- Valid
- Retrospective
- Prospective

Changes in policy and practice to reduce preventable harm from missed, delayed, wrong or over diagnosis

- Collective mindfulness
- Organizational learning
- Improved calibration
- Better measurement tools and definitions

Safer Diagnosis

Feedback for improvement

Improved value of health care

Improved Patient Outcomes

* Includes 8 technological and non-technological dimensions

Singh & Sittig BMJQS 2015
“A ‘diagnosis’ is not a static, fixed conclusion; it is a fluid, evolving conclusion based on serial observation and hypothesis building”

“One moves from less certainty to more certainty more or less quickly depending on a number of factors”

“Many of the complications introduced by both medicolegal and quality improvement efforts come from treating diagnosis as a black and white situation”
What Do We Do Now?

- Measure for quality improvement, learning & research
- Not ready for public reporting, performance measurement or penalties
- Still need more evidence and research in measurement
  - Good data, standards and operational definitions
- We need to go beyond the few institutions doing this
  - Others should start measuring for transparency
Targeting a High Priority Area

- Missed/delayed Cancer Diagnosis a safety concern
- Major reason: Lack of timely follow-up of cancer-related abnormal test results

Singh et al JCO 2010
Singh et al Am J Gastro 2009
'Trigger'-based Measurements

Patient-Primary Care Provider Encounter → Diagnostic Tests → More Patient-Provider Encounters → Consultations to Sub-specialists → Correct Diagnosis

Certain Diagnosis → Trigger

Uncertain Diagnosis
Why Triggers Are a First Step?

- Algorithms to select high-risk patient records for further reviews to look for missed opportunities
  - Picking up ‘needles in a haystack’ by making the haystack smaller
- Application retrospective or prospective surveillance

Singh et al JAMA IM 2013
Creating a Trigger-Based Safety Net

- Electronic health record (EHR)-based triggers look for follow-up actions on clues (or red flags) to detect delays prospectively

- Basic versions:
  - + hemoccult or microcytic anemia with no subsequent colonoscopy in 60 days
  - suspicious chest-x ray with no follow-up CT scan in 30 days

Murphy et al BMJQS 2013
Randomized Control Trial Results

- Intervention reduced delays in diagnostic evaluation of colorectal and prostate cancer

- More diagnostic evaluation by final review

Murphy et al. J Clin Oncology 2015
Time for Surveillance?

- Creating ‘intelligence’ related to diagnostic safety needs resource and time investment
  - Institutions/practices have too many competing priorities
  - Will it give bang for the buck outside of research?
Ten Strategies to Improve Management of Abnormal Test Result Alerts in the Electronic Health Record

Hardeep Singh, MD, MPH.† Lindsey Wilson, MA,* Brian Reis, BE,*

The Joint Commission Journal on Quality and Patient Safety

Misericordia University Health System, Scranton, Pennsylvania.†† Missoula, Montana. *†† University of Wisconsin, Madison.‡‡ Robert Wood Johnson University Hospital at Laundry Hill, New Brunswick, New Jersey.

National Patient Safety Goals

Eight Recommendations for Policies for Communicating Abnormal Test Results

Hardeep Singh, M.D., M.P.H.; Meena S. Vij, M.D.

Improving Test Result Follow-up through Electronic Health Records Requires More than Just an Alert

Dean F. Sittig, PhD† and Hardeep Singh, MD, MPH‡

†University of Texas – Memorial Hermann Center for Healthcare Quality & Safety, School of Biomedical Informatics, University of Texas Health Science Center, Houston, TX, USA; ‡Houston VA Health Services Research and Development Center of Excellence and The Houston VA Patient Safety Center of Inquiry, Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX, USA; §Section of Health Services Research, Department of Medicine, Baylor College of Medicine, Houston, TX, USA.

A recent American Medical Association report highlighted failures in communication of abnormal test results as an important but understudied facet of improving safety in ambulatory care.1 Because many outpatient test results are delivered in text form, it is possible that many providers fail to notice abnormal results.

In a related study, 28% of patients who had an abnormal test result received appropriate follow-up within 3 days in the intervention group (28% vs. 13% in controls). Neither group's laboratory follow-up rate was particularly encouraging.

On the bright side, both studies used distinctly different research approaches to reach similar conclusions, i.e., application of information and communication technologies, such as electronic health records (EHRs) with alerting capability, can increase the likelihood of appropriate test result follow-up. In paper-based systems, evaluating evidence of follow-up is itself challenging. On the other hand, both
Proactive Measurement

- The Office of the National Coordinator for Health Information Technology (ONC)-sponsored “Safety Assurance Factors for EHR Resilience (SAFER) project”
- Proactive risk assessment and guidance
- “1st draft” of best practices and knowledge
- Self-assessment; not meant to be regulatory
  - Focused on high-risk areas
  - Nine guides—all freely available

http://www.healthit.gov/safer

Singh et al BMC Med Inf 2013
As part of quality assurance activities, organizations monitor selected practices related to test result reporting and follow-up. Monitored practices include clinician use of the EHR for test results review and clinician follow-up on abnormal test results.

As part of quality assurance, the organization monitors and addresses test results sent to the wrong clinician or never transmitted to any clinician (e.g., due to an interface problem or patient/provider misidentification).
“The result was abnormal but I didn’t realize it. There’s a comment section but the doctor never leaves a comment. My triglycerides are high. Ok, what does that mean? What am I supposed to do?”

“I had to figure out the sodium was low. There’s a problem with low sodium, what can I do?”

“I’m not a doctor. I hope they’ll call if it’s problematic.”
Implications

- Patient engagement key in improving safety of test results follow-up
- Many opportunities for improvement in test results through portals
- We must preach “No news is not good news”
Take Away Points

- Diagnostic error will likely affect all of us
- Challenges to address them involve complex cognitive and systems issues
- Several opportunities for informatics interventions
Thank you and Acknowledgements

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- Multidisciplinary team at VA Health Services Research Center for Innovation

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