Considerations on Medical Error from an Epidemiologist’s Perspective

- Counting well is hard
- Comparing well is harder
- Predicting well is hardest

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Where to start reading on medical error?

Writings of physicians experiencing medical error as a patient or a patient’s relative are most illuminating

- Medical mistakes occurred at all levels of my care
  Itzhak Brook 3/18/13 KevinMD.com
- How I nearly MET my maker: A story of clinical futile cycles and survival
- What a new doctor learned about medical mistakes from her mom’s death
  Elaine Goodman ProPublica 1/9/13
- White Coat, Black Art with Dr. Brian Goldman – TED talk

Steps toward understanding include identifying:

1. Information resources
   - PubMed – journal titles, most with abstracts, many free papers
   - PSNet – Patient safety network
2. Naming (vocabulary) – what labels and definitions do people working in this area use?
   - Framing - ‘patient safety’ rather than ‘medical error’
3. Foundation (key) concepts for this topic
   - A ‘systems design’ and ‘culture’ problem more than an ‘individual error’ problem
4. Understanding the counting processes
   - How do I interpret the results for my situation?

For the physician perspective, two physician authors

For understanding systems, systems dynamics, and human function in these, two authors

W. Edwards Deming quotes:

- Learning is not compulsory . . . neither is survival
- You can’t manage what you don’t measure
- In God we trust; all others bring data
- Whenever there is fear, you will get wrong figures
Much patient safety work is modeled after aviation safety work.

Markers for 3,000 mi SF to NY Transcontinental Air Mail Route 70’ yellow arrows, 50’ gas light towers every 10 mi.


Human error: models and management
Reason J. BMJ 320:768-770, 2000

“Swiss Cheese” model
Newer – STAMP, STPA, safety engineering models
http://en.wikipedia.org/wiki/Safety_assurance

SEIPS 2.0: A human factors framework for studying and improving the work of healthcare professionals and patients

SEIPS 2.0 Model
http://dx.doi.org/10.1080/00140139.2013.838643

Chap. 14 The Paradox of Error, pg. 300
- “According to the Institute of Medicine, between 690,000 and 748,000 patients are affected by medical errors every year and between 44,000 and 98,000 die….”
- Even the lowball estimate makes medical mistakes the eighth leading cause of death
- . . . worse than breast cancer, AIDS, and motor vehicle accidents . . . . a sold-out 747 crashing every 3 days

Results of some counting process Presented as “Dangling Numerators”, which are dangerous to your thinking!

Three choices upon reading something surprising, alarming, or important

Accept author’s conclusions at face value
Critically evaluate the evidence to understand the author’s conclusion
Reject author’s conclusions out of hand

Requires Time & Skill
Cost of improving understanding
Cost of insufficient understanding
Results of many counting processes are widely reported but often not critically understood

For a more useful mental concept, convert “dangling numerators” to risk probabilities

\[
\text{Risk} = \frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{No. individuals experiencing event}}{\text{No. individuals at risk over interval}}
\]

- **Risk**: Probability that an “at risk” (exposed) individual experiences the event in the defined time interval
- **Event**: The occurrence of interest – e.g., getting married, sick, dying, graduating
- **Time Interval**: Day, Month, Year, lifetime
- **Risk Factor**: An individual characteristic or environmental factor (exposure) that increases or decreases the risk of the event for the individual
- **V.I. Rule**: Everyone in the denominator must have the potential of being in the numerator and everyone in the numerator must be in the denominator!

Use the Fermi problem approach to gain a deeper understanding

Notes: 300 According to the Institute of Medicine
LT Kohn, MS Donaldson, eds. To Err is Human: Building a Safer Health System, the National Institute of Medicine (NAP, 2000), 26.

- This is the source for the number of people killed by medical error and for the ranking among causes of death
- The total number affected by medical error is an extrapolation [prediction]
- A million patients are affected by “adverse events” that include medical error
- Contracting post-operative pneumonia counts as an adverse event but not a medical error unless a mistake led to the infection
- Those affected by medical error accounted for 58% and 68% of the total adverse events

What’s needed for understanding?

Identify Hermagoras’s “seven circumstances” for the components of understanding

- **quis, quid, quando, ubi, cur, quem ad modum, quibus adminiculis**
  Who, what, when, where, why, in what way, by what means, to whom it helps?
- **I keep six honest serving-men**
  (They taught me all I knew): Their names are What and Why and When And How and Where and Who. Rudyard Kipling, 1902
  Ask “Five Why’s?” for the depth of understanding
- **Five iterations of asking “why?”** usually gets to the root cause

Powerful stakeholders have opposing motives to influence counting processes and to spin their outcomes
To Err is Human: Building a safer health system, 26.

2 – Errors in Health Care: A Leading Cause of Death and Injury

A study of 1984 New York hospital admissions and 1992 Colorado and Utah hospital admissions found that 3 and 4 percent experienced an adverse event, defined as injuries caused by medical management. 1

The proportion of adverse events due to errors (PAE - preventable adverse events) was 58% in New York, and 53% in Colorado and Utah. 2

Extrapolated to 34 million 1997 hospital admissions, this implies that at least 44,000 and perhaps 98,000 die annually because of hospital medical errors. 3

Even using the lower estimate, hospital deaths due to PAE exceed the number due to the 8th-leading cause of death. 4

Deaths due to PAE exceed the deaths due to motor vehicle accidents (43,000), breast cancer (42,000) or AIDS (17,000). 5

[All numbers rounded for easier readability and recall]
IOM report cites 5 primary sources for this section:

See also: Leape, 1991, Thomas, 2000


- BACKGROUND: As part of a study of medical injury and malpractice litigation, we estimated the incidence of adverse events, defined as injuries caused by hospital care, and the subgroups of such injuries attributable to negligence and substandard care.
- METHODS: We reviewed 36,128 randomly selected medical records of 31,578 randomly selected acute care, non-psychiatric hospitalized patients from 1984.
- RESULTS: Adverse events occurred in 11.4% of hospitalizations, and 38% were due to negligence. Although 70% led to disability lasting less than 6 months, 3% caused permanent disabling injuries and 14% led to death.
- The percentage of adverse events attributable to negligence increased in the categories of more severe injuries. We estimated that among the 2,671,863 patients discharged from New York hospitals in 1984 there were 38,009 adverse events and 27,179 resulted in negligence.
- The percentage of adverse events due to negligence was markedly higher in the elderly.
- CONCLUSIONS: There is a substantial amount of injury to patients from medical management and many injuries are the result of substandard care.

Going to the full primary paper, which is free on-line:

“We excluded events caused during the initial 1984 hospitalization but discovered at a subsequent hospitalization”

“We have presented our methods of record review and our sampling strategy in detail elsewhere.”


- To be defined as an adverse event, it must have produced disability that prolonged the hospital stay or reduced function at discharge
- We undersampled births with normal deliveries, which were numerous
- We undersampled patients over the age of 70, for whom economic impact as measured by the courts is less variable than for younger patients
- We oversampled births with complications and cases treated by physicians in high-risk specialties

Records were not randomly selected with equivalent probability as implied by the previous abstract!

Going to on-line site of the third reference, AHA:

Hospital Facts to Know (AHA, 2008):
- Every year in 5,815 hospitals (AHA, 4,973 hospitals HJ Kaiser):
  - 35 million people admitted
  - 4 million babies delivered
  - 118 million people treated in emergency departments
  - 481 million other outpatients provided care
- National Non-federal Hospital Utilization Survey, CDC 2010
  - 35 million discharges, 11.4 per 100 people, 4.8 day stay
  - 130 million emergency department visits, 42.8 per 100
  - 17.2 million resulted in admission, 2.3 million critical care
  - 101 million outpatient visits, 33.2 per 100

http://kff.org/other/state-indicator/hospitalizations/
http://www.cdc.gov/nchs/data/hotlinks/hospital.htm

Considering the 4th and 5th references, CDC National Vital Statistics Reports for 2010:

10 leading causes accounting for 75% of US deaths in rank order:
1. Heart diseases
2. Malignant neoplasms
3. Chronic lower respiratory diseases
4. Cerebrovascular diseases
5. Accidents (unintentional injuries)
6. Alzheimer’s disease
7. Diabetes mellitus
8. Nephritis, nephrotic syndrome and nephrosis
9. Influenza and pneumonia
10. Intentional self-harm (suicide)

Methods:
- Based on death certificates filed in the 50 states in 2010
- Cause is classified by the International Classification of Diseases (ICD-10)
- Rankings differ by age, sex, race, and Hispanic origin [intrinsic risk factors]

Table 1: 2010 US Deaths, 20 – 24 years of age

<table>
<thead>
<tr>
<th>Race</th>
<th>Gender</th>
<th>#1 cause - Death rate per 100,000</th>
<th>All causes - Death rate per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian or Pacific Is.</td>
<td>female</td>
<td>4.6</td>
<td>18.0</td>
</tr>
<tr>
<td></td>
<td>male</td>
<td>19.4</td>
<td>55.3</td>
</tr>
<tr>
<td>Black</td>
<td>female</td>
<td>14.1</td>
<td>57.3</td>
</tr>
<tr>
<td></td>
<td>male</td>
<td>93.0</td>
<td>189.3</td>
</tr>
<tr>
<td>Hispanic</td>
<td>female</td>
<td>11.1</td>
<td>32.6</td>
</tr>
<tr>
<td></td>
<td>male</td>
<td>42.1</td>
<td>97.9</td>
</tr>
<tr>
<td>Native American</td>
<td>female</td>
<td>23.1</td>
<td>53.7</td>
</tr>
<tr>
<td></td>
<td>male</td>
<td>63.2</td>
<td>147.5</td>
</tr>
<tr>
<td>White</td>
<td>female</td>
<td>22.2</td>
<td>46.5</td>
</tr>
<tr>
<td></td>
<td>male</td>
<td>63.0</td>
<td>123.2</td>
</tr>
</tbody>
</table>

How good are death certificates for counting?

- We found reasonably good agreement between death certificate diagnoses and histologically confirmed cases, $r$ coefficient 0.86

- All methods for identifying TB-related deaths using death certificate data overestimated the number of TB-related deaths compared to the tuberculosis registry
- The positive predictive value ranged from 22% for a TB ICD-10 code as an underlying or multiple cause of death to 56% for TB listed in the direct cause of death text field
- Seventeen (33%) of 51 subjects assigned with a TB ICD-10 code as an underlying or multiple cause of death had no evidence of TB on the death certificate and were not present in the TB registry

US Death Certificate instruction section (partial)

PART I (Chain of events leading directly to death)
- ALWAYS enter the underlying cause of death on the lowest used line in Part I
- For each cause, indicate the interval between the presumed onset and the date of death. The term “unknown” or “approximately” may be used
- The terminal event (for example, cardiac arrest or respiratory arrest) should not be used. If a mechanism of death seems most appropriate to you for line 4, then you must list its cause(s) on the line(s) below it (for example, cardiac arrest due to coronary artery atherosclerosis or cardiac arrest due to blunt impact to chest)
- If an organ system failure such as congestive heart failure, hepatic failure, renal failure, or respiratory failure is listed as a cause of death, always report its etiology on the line(s) beneath it (for example, renal failure due to Type I diabetes mellitus)
- When indicating neoplasms as a cause of death, include the following: 1) primary site or that the primary site is unknown, 2) benign or malignant, 3) cell type or that the cell type is unknown, 4) grade of neoplasm, and 5) part or lobe of organ affected
- Always report the fatal injury (for example, stab wound of chest), the trauma (for example, transection of subclavian vein), and impairment of function (for example, air embolism)
- PART II (Other significant conditions)
- Enter all diseases or conditions contributing to death that were not reported in the chain of events in Part I and that did not result in the underlying cause of death
- If two or more possible sequences reached in death, or if two conditions seem to have added together, report in Part II the one that, in your opinion, most directly caused death. Report in Part II the other conditions or diseases

My goals were to provide:
- Entry points and Google or Bing targets for pursuing the topic of medical errors
- Strategies for developing a deeper understanding of the topic
- A basis for considering the counting processes associated with the topic
  - Counting well is harder than you might think
  - Comparing well is even harder
  - Predicting well is the hardest of all

“Let’s be careful out there”

Hill Street Blues’s Sergeant Eberhaus’s roll call close (Michael Conrad)

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http://www.vetmed.wsu.edu/courses-jmgay/
Five recent reviews on medical error and patient safety: