Buyer Beware: How far can you trust health choices information broadcast to the public?
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The Patients’ Question Before the Internet Public Information Age

• Doctor, what should I do?
The Patients’ Questions in the Internet Public Information Age

• What are the relative merits of my options?
• Where might I have that procedure done?
• How far can I trust your advice?

What is the Quality of the Internet’s Advice on Hospital Quality?

Documented concerns…

• 3 non-proprietary sites were free, didn’t require joining; 3 proprietary sites tended to rate lower on these aspects
• All identify data sources; nonproprietary sites alone fully described statistical methods used; just one site was judged to provide reproducible risk adjustment
• Many limitations noted (age of data, too limited a range of measures to sufficiently represent overall quality of care, etc.)
• Best to worst ranking of 4 hospitals by the 3 proprietary websites is consistent for laparoscopic cholecystectomy, but inconsistent (colectomy) or not possible due to lack of data (hernia repair)

started many years ago…
What is the Quality of Popular Advice on Maintaining Your Health?

Key findings

- The Dr. Oz Show averaged 12 recommendations per episode, and The Doctors 11. Most common was dietary advice on The Dr. Oz Show (39%) and consult a healthcare provider on The Doctors (18%).
- For recommendations in The Dr. Oz Show, evidence supported 46%, contradicted 15%, and was not found for 39%.
- For recommendations in The Doctors, evidence supported 63%, contradicted 14%, and was not found for 24%.
- Believable or somewhat believable evidence supported 33% of recommendations on The Dr. Oz Show and 53% on The Doctors.
- A specific benefit was described for 42% and 41% of recommendations on the shows respectively. Magnitude of benefit was described for 17% of recommendations on The Dr. Oz Show and 11% on The Doctors.
- Disclosure of potential conflicts of interest accompanied 0.4% of recommendations.
A Few Observations Regarding Evidence-Based Medicine

Evidence doesn’t exist to support all medical decisions, but...

• Half of 1,500 lay people had read about medical research studies helping doctors know what works best
• 34% recalled ever having a doctor discussing research studies on what works best
  – Many thought care decisions are based on the evidence of just their own test results & medical history
• Many thought clinical practice guidelines were rigid rules

What is Evidence?

Information that is:

• Necessary
  – As Specific to the Question
    • Content & Construct Validity
• Sufficient
  – Considering limits to interpretation
• Persuasive
  – Internal validity
    • sufficiently precise, accurate & reliable
  – External validity
    • safe to generalize
  – Motivating but Honest Presentation

Results from a range of types:

• Anecdotal observation
• Case description
• Case series
• Observational studies
  – Retrospective
  – Prospective
• Blinded randomized controlled intervention studies
What Makes Convincing Evidence that “A” Causes “B”

Assessing These Criteria:

- **Strength**
  - The larger an association the more likely that it is causal
- **Consistency**
  - Consistent findings observed by different persons in different places with different samples
- **Specificity**
  - The more specific an association between a factor and an effect, the bigger the probability that factor is truly a cause
- **Temporality**
  - The effect has to occur after the causal exposure
- **Biological gradient**
  - Greater exposure should generally lead to greater incidence
- **Plausibility**
  - A plausible mechanism between cause and effect is helpful (recognizing possibility of limited current knowledge)
- **Coherence**
  - Coherence between epidemiological and laboratory findings increases the likelihood of an effect
- **Experiment**
  - Occasionally it is possible to find experimental evidence
- **Analogy**
  - The effect of similar factors may be considered

Sir Austin Bradford Hill

How Strong is the Body of Evidence to Answer a Specific Question?

Cochrane Library maintains formal reviews

GRADE evidence tables assess:

- Risk of bias
- Publication bias
- Imprecision (random error)
- Inconsistency
- Indirectness
- as well as showing magnitude of effect estimates

http://www.thecochranelibrary.com/view/0/index.html

http://www.gradeworkinggroup.org/
Wouldn’t you like your own doctor to

• Let you know the strength of evidence behind a treatment recommendation
  – When the advice is solidly supported by studies
  – When the advice is consistent with limited scientific knowledge
  – When the advice is solely professional judgment
• Give you a quantitative risk-benefit estimate of
  – the size of risk if untreated, and
  – size of benefit if treated, and
  – magnitude of any adverse aspects of treatment

Misguided Action Based on Bad Evidence Has Negative Consequences

The legacy of:
• Wakefield’s discredited research re: MMR vaccine
• Indirect target events in place of desired outcomes
• Conflicting guidance about PSA screening test
  ➢ Measles outbreaks where previously measles-free
  ➢ [https://www.youtube.com/watch?v=TMjnEFrrTjY](https://www.youtube.com/watch?v=TMjnEFrrTjY)
  ➢ More harm than benefit, added cost & confusion
Healthcare-Associated Infections
Mandatory Public Reporting

What is meaningful to people?

- Best practices to watch for and questions to ask in order to protect yourself?
- Hospital-specific infection rates?
- Ratios of hospital-specific infection rates?
- Surgeon-specific infection rates?
- Something else entirely?

Standardized Infection Ratio?

Is HAI Public Reporting Trustworthy?

- Consistent with ISO 2859
- Maintain pass/fail standard for sensitivity and specificity
- “External” site visits prioritized by “Internal” validation results
  - All hospitals accountable
- Workload sustainable among 65 WA hospitals 2010-2014
- Hospitals exceeded minimum reporting standards

CDC/NHSN Validation Guidance & Toolkit (2012, 2013)
- Inconsistent with MIL, ANSI, ISO
- No pass/fail standard
  - Insufficient power to estimate accuracy?
- Internal validation step not linked
  - Selection by sampling from SIR ranks
  - Selection bias toward large hospitals?
- Workload & sustainability unknown
  - 0 states willing to try in 2012
  - 4 in 2013 & 3 in 2014 with ELC/ACA $$$
  - Might be 2-4 times more work than Washington State protocol

2 Lempp JM, et al., Cost of a Sustainable Annual Validation Process to Ensure Credibility of State HAI Reporting. CSTE 2014, Poster #135
Today’s Statutory & Regulatory Authority Environment

Today’s Statutory & Regulatory Authority Environment: Central Role of NQF
Credible Validation is Essential

Why spend taxpayer dollars on validation reports that begin like this one?

- “Resources for this audit were limited to a review of 200 patient records. Determination of an appropriate sample size is difficult and the sample size (202) is too small to draw statistically significant conclusions about the validity of CLABSI data reported to NHSN.”

Why use validation methods that won’t satisfy certified quality professionals?

Process Validation to Minimize “Producer’s Risk” & “Consumer’s Risk”

Validation has a technical meaning:

  - “The act of confirming a product or service meets the requirements for which it was intended.”

- Definition from A Dictionary of Epidemiology, 5th Edition (International Epidemiological Association)
  - “The process of establishing that a method is sound.”

Validation is related to, but not the same thing as:

- Audit
- Data Cleaning
- Inspection
- Verification
Validation in Other Industries

• **Acceptance sampling** uses statistical sampling to determine whether to accept or reject a production lot of material. It has been a common quality control technique used in industry and particularly the military for contracts and procurement.
  
  – 1930s
    • Dodge-Romig acceptance sampling tables
  – 1940s
    • MIL STD 105A
  – 1990s
    • MIL STD 105E cancelled, ANSI/ASQ Z1.4 in U.S.
    • ISO 2859 as international equivalent
What Can Everyone Do Now?

• Mandatory public reporting arose because of consumer pressure on politicians
  – Credible validation can be promoted to ensure value of the investment

• All hospital quality metrics proposed by federal agencies must pass through the National Quality Forum
  – NQF can be encouraged to create a credible validation metric with the American Society for Quality’s Health Care Division as its steward