Buyer Beware: How far can you trust health choices information broadcast to the public?

Northwest Patient Safety Conference 2015 David Birnbaum, PhD, MPH

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...



Leonardi MJ, McGory ML, Ko CY. ARCH SURG 2007;142(9):863-9

tly included in this study if they met 3 inclusion criteria. The site needed to (1) rank and compare hos-pitals based on surgical quality measures, (2) rank hospitals search, but not included in this study, were insuran-company sites that provided a regionally restricted ho pital comparison tool available only to their enrollee

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Measure ^a	Web Site ^b					
	CMS	JCAHO	Leapfrog Group	A	в	С
Accessibility						
Free	Yes	Yes	Yes	No	No	Yes
No sign-up	Yes	Yes	Yes	No	No	No
Ease of identification	Yes	Yes	Yes	No	Yes	No
Transparency						
Data sources given	Yes	Yes	Yes	Yes	Yes	Yes
Statistical method reproducible	Yes	Yes	Yes	No	No	No
Risk adjustment method reproducible	NA	NA	Yes	No	No	No
Appropriateness						
Process measures	Yes	Yes	Yes/no ^c	Yes	No	No
Structure measures	No	No	Yes	Yes	No	Yes
Outcome measures	No	No	Yes/no ^c	Yes	Yes	Yes
Procedure-specific measures	No	No	Yes	Yes	Yes	Yes
Patient may prioritize ranking criteria	No	No	No	Yes	No	Yes

reviations: CMS, Centers for Medicare and Medicald Services; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; NA, data not

utable. *For timeliness, all data were more than 1 year old. "Web sites A thorugh C were proprietary and their names and URLs were withheld. *Only coronary artery bypass grafting.

Another commonly identified category of Web site not included in this study was state-specific quality com-parison sites (eg, the New York State Coronary Artery Bypass Grafting Reporting System).

WEB SITE ACCESSIBILITY

the same data could not repeat their calculations and du-plicate their results). In addition, some of their quality mea-sures were ill defined. For example, the term *complica*-tions was used and loosely defined, but it was not clear whether a higher than expected complication rate for coro-menter term horecomplicity means that a horecital hold mean pass grafting means that a hospital had n

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%)
 - 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 - 53% on The Doctors.
- A specific benefit was described for 43% 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
- Specificity
 The proceeding file of proceeding between a faster and an
 - effect, the bigger the probability that factor is truly a caus **Temporality**
- The effect has to occur after the causal exposur
 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 experiment
 - 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.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
- <u>https://www.youtube.com/</u> 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?

NOL AND MOSPITAL EPIDEMIOLOGY MARCH 2011, VOL. 32, NO. 3

ORIGINAL ARTICLE

SIR, You've Led Me Astrav!

David Birnbaum, PhD, MPH; Roxie Zarate, MPH; Anthony Marfin, MD, MPH, MA

ACCGOUND. The standardized infection ratio (SIR) is an indirectly standardized morbidity ratio that has been used to comp faction rate in a hospital with an expected number of infections from a national standard and is being increasingly pomoted as a structure. To identify potential discognation Heatons Heaton and the measures of risk,

THODS. Hypothetical and real data were compared using relative risk, a directly standardized morbidity ratio, and SIR values acros

a range of varying hospital population compositions. sturs. In real and hypothetical data, other summary statistics were consistent with each other and with underlying HAI incidence unsity rates. However, use of the SIR frequently led to conclusions inconsistent with these other inherently unbiased estimators.

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The standardized infection ratio (SIR) is an indirectly stan-showere net formally trained in epidemiology to a graduat landized mobility ratio (SIR) that was introduced more lard tended to interpret such repression (COC) and a repre-tation of the standard standard standard standard standard standard standard interfaces in a longith unit an expected correstreated one of giving a single SiR where for earth lard measurism blood procedure-specific rates completed from all hospital partici-stration in the standard regional standard standar

Is HAI Public Reporting Trustworthy?

Washington State

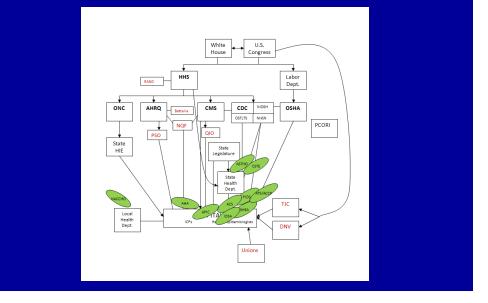
- Consistent with ISO 2859
- Maintain pass/fail standard for sensitivity and specificity
- "External" site visits prioritized by "Internal" validation results
 - All hospitals accountable
- Workload sustainable among 65 WA hospitals 2010-2014²
- Hospitals exceeded minimum reporting standards ³

CDC/NHSN Validation Validation Protocol (2010, 2015) Guidance & Toolkit (2012, 2013)

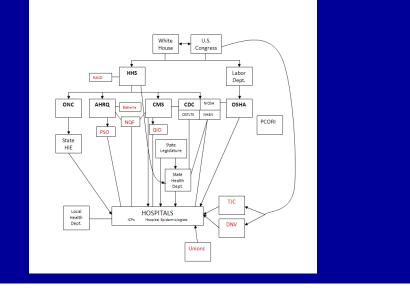
- Inconsistent with MIL, ANSI, ISO
- No pass/fail standard
 - · Insufficient power to estimate accuracy?
- Internal validation step not linked Selection by sampling from SIR ranks ¹ o Selection bias toward large hospitals?
- Workload & sustainability unknown
 - 0 states willing to try in 2012
 - 4 in 2013 & 3 in 2014 with ELC/ACA \$\$\$
 - Might be 2-4 times more work than Washington State protocol

Birnbaum DW, Zarate R, Marfin A. SIR, You've Led Me Astray!. INFECT CONTROL HOSP EPIDEMIOL 2011;32(3):276-282. ² Lempp JM, et al.. Cost of a Sustainable Annual Validation Process to Ensure Credibility of State HAI Reporting. CSTE 2014, Poster #135 ³ Lempp JM, et al.. Distribution of Central Line Associated Bloodstream Infections in Washington State, 2009-2013. CSTE 2014, Poster #137

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?

COMMENTARY

The Current State of Validating the Accuracy of Clinical Data Reporting: Lessons to Be Learned from Quality and Process Improvement Scientists

Joseph A. Furtuna, MD;¹ William A. Brenneman, PhD;² Sandra Steeli, MS, CMQOE; David Birahaum, PhD: MPH;⁴ Nay L. Brown, CSSGB¹

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ine L. American Society for Quality (ASQ) Healthcare Dirition, MI Obio; X. Abbell Point of Gare and ASQ Audit Division, Princeton, A Insent of Haulth, Diversia, Wednigston, S. Haardand Kidner Nete

Bendro, K., and Jackinson B. 2009 and J. 2009 and 2009

Process Validation to Minimize "Producer's Risk" & "Consumer's Risk"

Validation has a technical meaning:

- **Definitions from Quality Glossary, American Society** for Quality, available at http://asq.org/glossary/
 - "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

- <u>Acceptance sampling uses statistical sampling to determine</u> 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

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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