Evidence Based Surgery

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Credits

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- Susan Kaiser, M.D., FACS – Mt. Sinai School of Medicine, NY
- David Slawson, M.D. – Professor of Family Medicine, University of Virginia School of Medicine

Information Mastery

Feeling “Good” About
Not Knowing Everything

What is EBM?

EBM is the “ conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. ”

D. L. Sackett, 1996

Why bother with EBM?

- New and good evidence is constantly being generated.
- Although we need this new evidence very often dealing with patients, we often don’t get it.
- Therefore our databases, and thus our clinical performance, deteriorate over time.
  - Much like the inventory of a bread store which goes stale after time.

Answers to the Question: Why Bother?

1. Because it keeps us at the top of our field.
2. Because it enhances our confidence in clinical decision making.
3. Because it serves the patient's best interest.

How about the traditional way?

- Textbooks: By the time they are available, they are out of date.
- CME courses: Even though they increase knowledge, they do not improve patient outcomes.
- Experts/colleagues: There is no way to evaluate their validity and reliability.

Compared to other approaches

- Faith approach
  - It works because I say it works
    - **“He/she is often wrong but never in doubt!”**
  - In my experience
  - It’s the standard of practice
- Reasoning approach
  - (Flexner report 1910) promoted education based on pathophysiology
  - It ought to work; it makes sense

EBM

A New Paradigm Shift in Medicine...

Clinicians as “informed consumers”
of medical research.

Phase 2 of the newer paradigm…

Clinicians as “informed consumers” of
“meta-analysis” research

Medical Information System

Journals/Research

"Throwaways"

Monograph

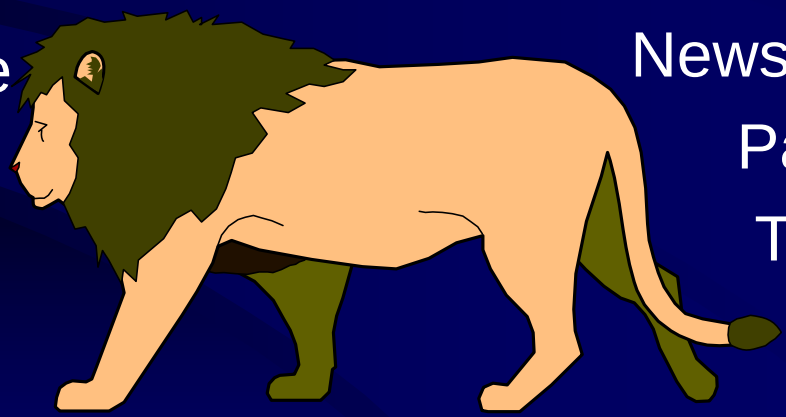
Practice Guidelines

CME courses

Clinical Experience

Colleagues

It's a jungle out there !



Pharmaceutical Reps

Computers

Audiotapes

Newsletters

News media

Patients

Textbooks

Traditional “EBM” Step Approach

The Usual Pathway to the Truth:

- Step 1: Formulate a question
- Step 2: Seek out the evidence
- Step 3: Critically appraise the evidence
- Step 4: Implement Information into practice

(McMaster’s approach and JAMA series)

“Evidence Prescription” – Susan Kaiser, MD, PhD, FACS

Format for a clinical question

"In a _____patient with _____, how does _____ compare to _____ in terms of _____?

Example of a clinical question

"In a **21 year old woman** with **asymptomatic gallstones and no known medical problems**, how does **observation** compare to **cholecystectomy** in terms of **short-term and long term morbidity and mortality?**

Search for the Evidence

- Seems like the most inconvenient and time-consuming.
- Goal: Find all or almost all of the available relevant evidence.
- Just finding one or two articles is NOT ENOUGH…..especially if the studies are not good!

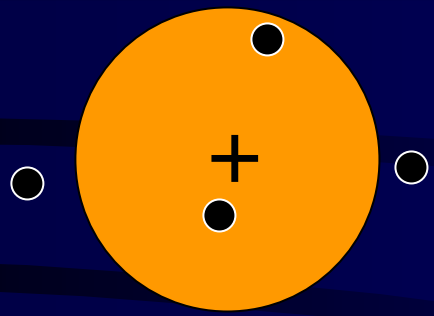
Search Ideas

- Web sites
  - PubMed
  - Medline
  - http://SUMSearch.uthscsa.edu/searchform4.htm
  - http://home.mdconsult.com/php/4043383/home.html
  - Try Google!
- Standard reference texts and paper journals
- Etc.

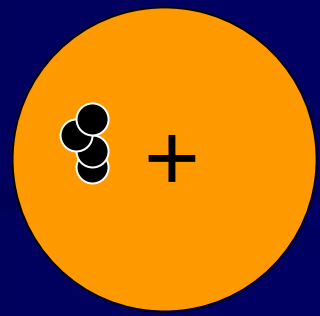
Evaluate the Evidence "Critical Appraisal"

- Evaluate the validity and reliability of the data in the article:
  - Is the result real?
  - Is the result reproducible?
  - Is it meaningful – does it matter?
- Application of the scientific method

Validity and Reliability



Invalid and unreliable



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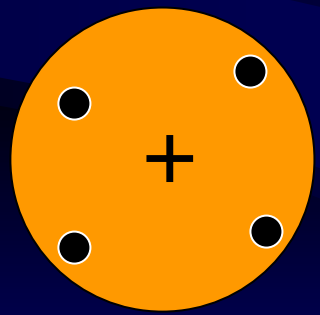

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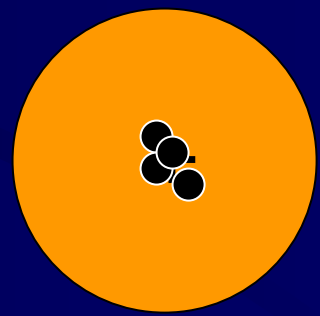


Valid and reliable

Critical Appraisal

- What are the flaws in the study?
  - Fatal?
  - Discard results?
- Evaluate according to a very high standard ….. We accept less, sometimes a lot less.

Distinguish Types of Data

- Flawed data can be evaluated and sometimes provide guidance.
  - Example: Multiple case reports of an obscure entity.
- If there are no data, it isn't evidence.
  - Example: An undocumented opinion piece in Prevention Magazine…..or the NEJM!
  - Example: Anecdotal reports about benefits of …….

Levels of Evidence

I. Evidence obtained from at least one properly randomized controlled trial

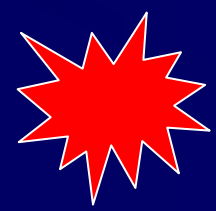
II. Non – randomized studies

1. **Evidence obtained from well-designed trials without randomization**
2. **Evidence obtained from well-designed cohort or case control analytic studies, preferable from more than one research group.**
3. **Evidence obtained from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments (i.e., penicillin)**

III. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Virtually all studies have at least some minor flaws…..

- Beware of the fatal flaw that invalidates the results.
- Examples:
  - Choosing the wrong comparison group
  - Serious failures of randomization, non-concealed allocation
  - “results” not supported by the data



Apply the Evidence
Implement into Practice

- Go back to the clinical question…..
- Is there enough evidence to make a good choice?
- Can the evidence be applied to *our* patient?

- How confident are you of the study results, given your assessment of their validity and reliability?
- Are the subjects in the studies sufficiently similar to our patient to make the results applicable?

Potential Danger

- See an article that says “YES”
- Miss 5 studies that say “NO”

- Apply this technique to areas of medicine which are not necessarily data-driven or easily assessed with data.

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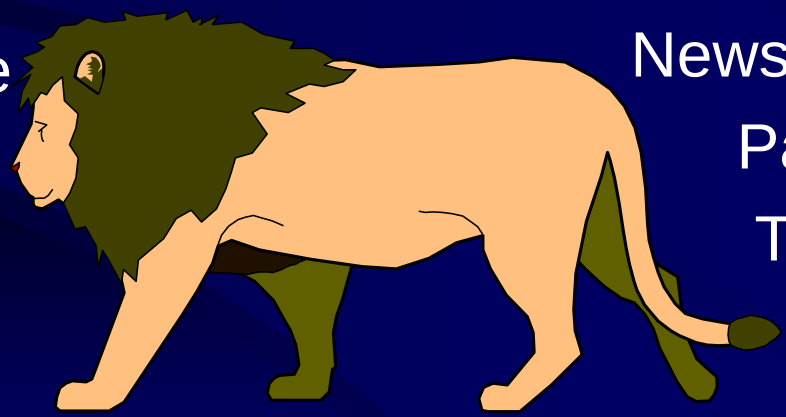

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Information Anxiety

"The frustration that occurs
when there is a great deal of information,
but it doesn't tell us what we want
or need to know."

-Richard Wurman

Newer Paradigm - start with "Why?"

- Foraging: To keep up with the new
  - » Typically deals with searching reviews
- Hunting: To answer a specific question
  - » Typically deals with reading the literature

2 Other methods:

- Retracing: To review previous learned info
- Sporting: To keep up with your interests

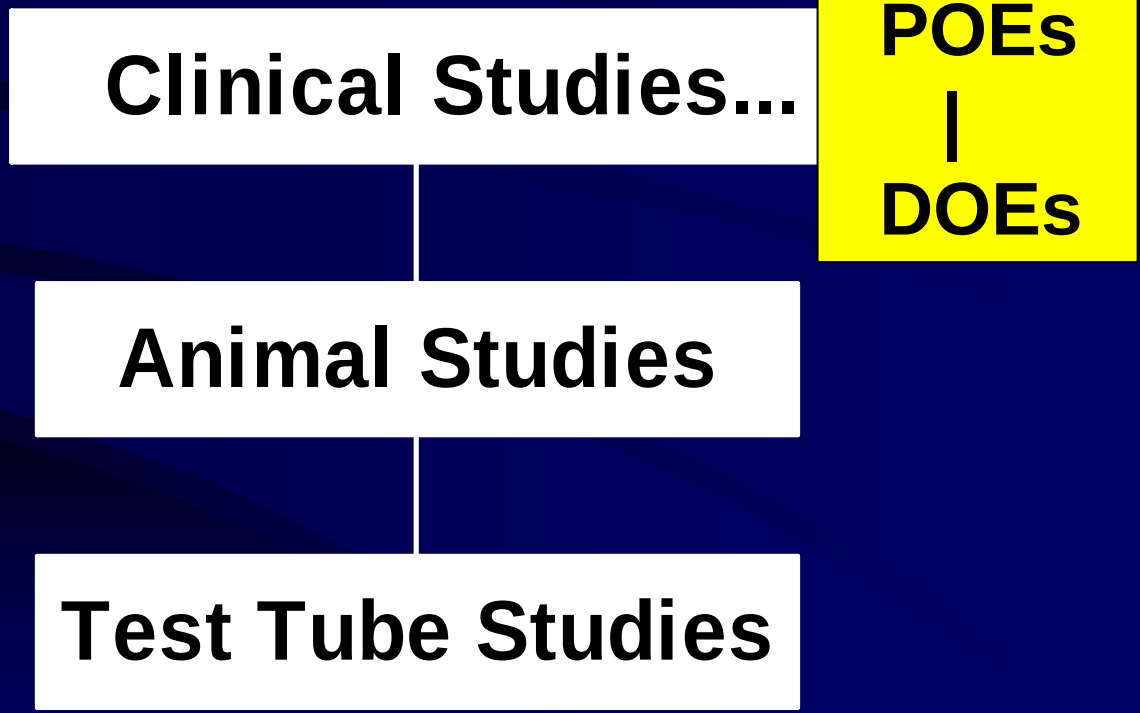
Different strategies for each one.

Key to Info Mastery

The Usefulness of any source = $\frac{\textit{Relevance X Validity}}{\textit{Work}}$

Relevance

Hierarchy of Evidence



Disease Oriented Evidence DOEs

- Outcomes of pathophysiology, pharmacology, etiology
- Focus on #s and tests
- Requires assumptions
- Example:
  - tight glucose control of type I diabetics decreases proteinuria

Patient Oriented Evidence
POEs

- Measures outcomes important to patients: morbidity, mortality, quality of life, costs
- Final outcomes
- No assumptions required
- Example:
  - tight glucose control of type I diabetics reduces their need for dialysis &/or prolongs their life

POEMS

- Patient - Oriented Evidence that Matters
- Matters to the patients
- Matters to you, the clinician, because if valid, will require you to change your practice.

Key to Info Mastery

The Usefulness of any source = $\frac{\textit{Relevance X Validity}}{\textit{Work}}$

Validity

Work

Making the Most of Original Research - Foraging

- Minimize *Work* in the forage mode
  - Scan POEM bulletin boards
    - ACP journal club, EBM, JFP POEMS, Evidence based practice
  - Concentrate on high-yield journals (high POEM:DOE ratio)
    - 10% journals - the highest ratio
    - JAMA, Ann Int Med, NEJM, JABFP, JFP, Arch Int Med, BMJ, Am J EM Med

HUNTING

Minimize *Work* in the hunting mode…

- Look to the meta-analysis reviews
- Cochrane Library
- Practice Guidelines
- Point of Contact reviews

Cochrane: Comprehensive Search of Meta-analyses

- Randomized Control Trials (RCT)
- Emphasis on Double Blinded samples
- If do only a Medline search:
  - miss 50% RCTs in Index Medicus
- Development of Control Trials Registry
  - 1st year: 22,000 citations (1985-1993)
  - In 1998: 250,795 citations
  - Ongoing update: mandatory every 2 years

Cochrane Meta-analyses characteristics:

- A standard format for review preparation
- A protocol approach process with strict criteria
- The format allows easy scanning for identifying the validity data
- Invites comments after publication

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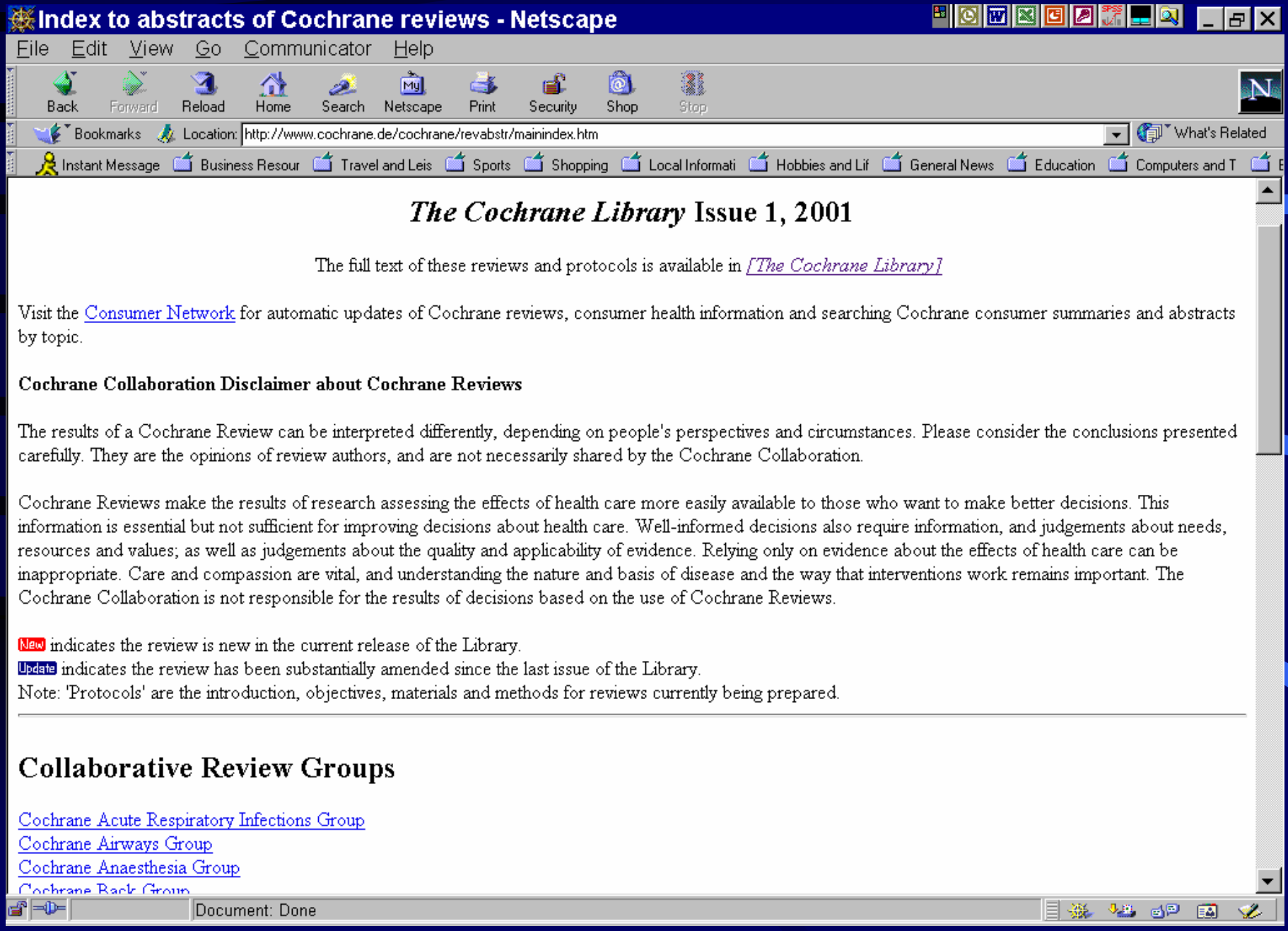
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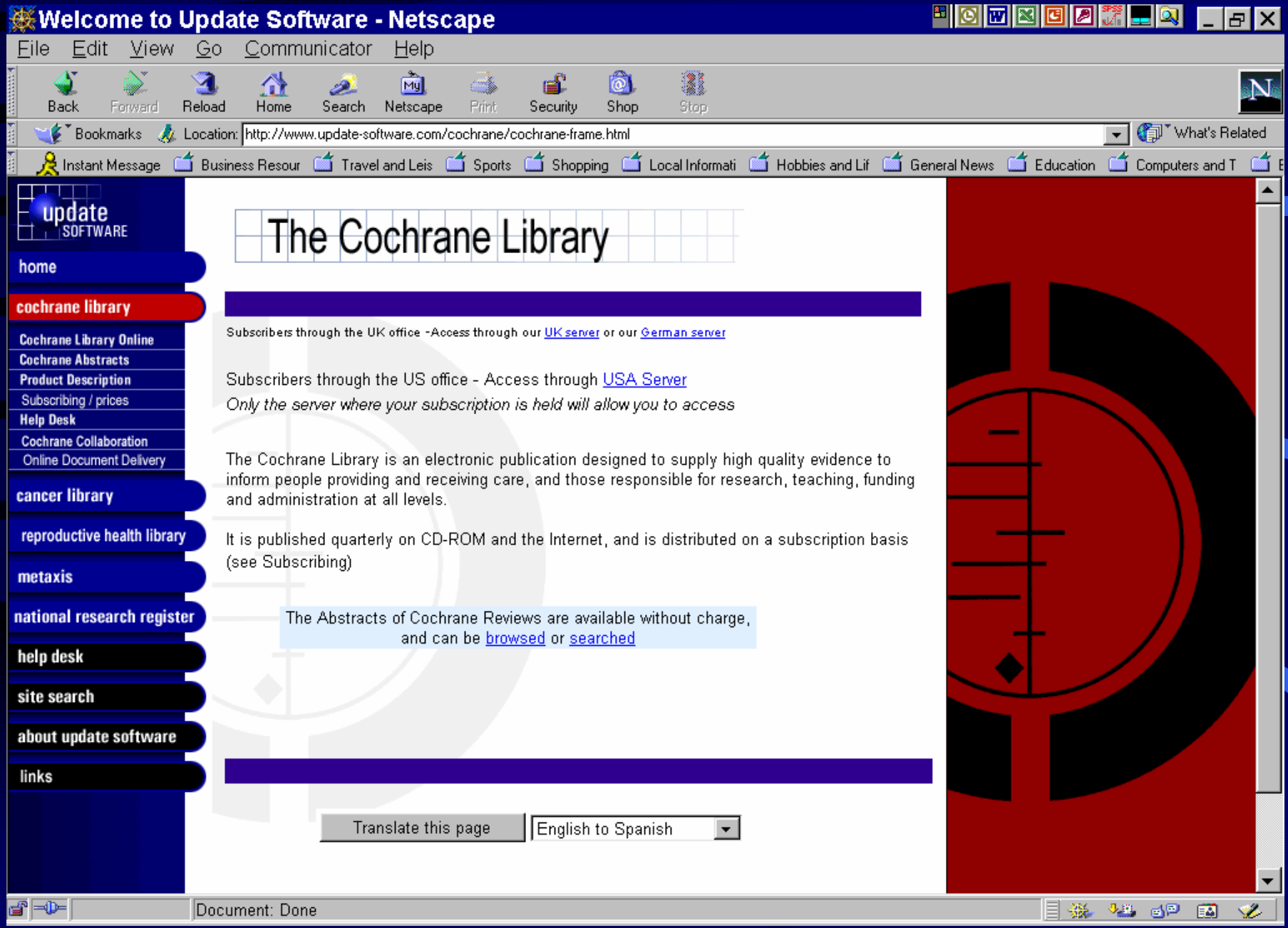
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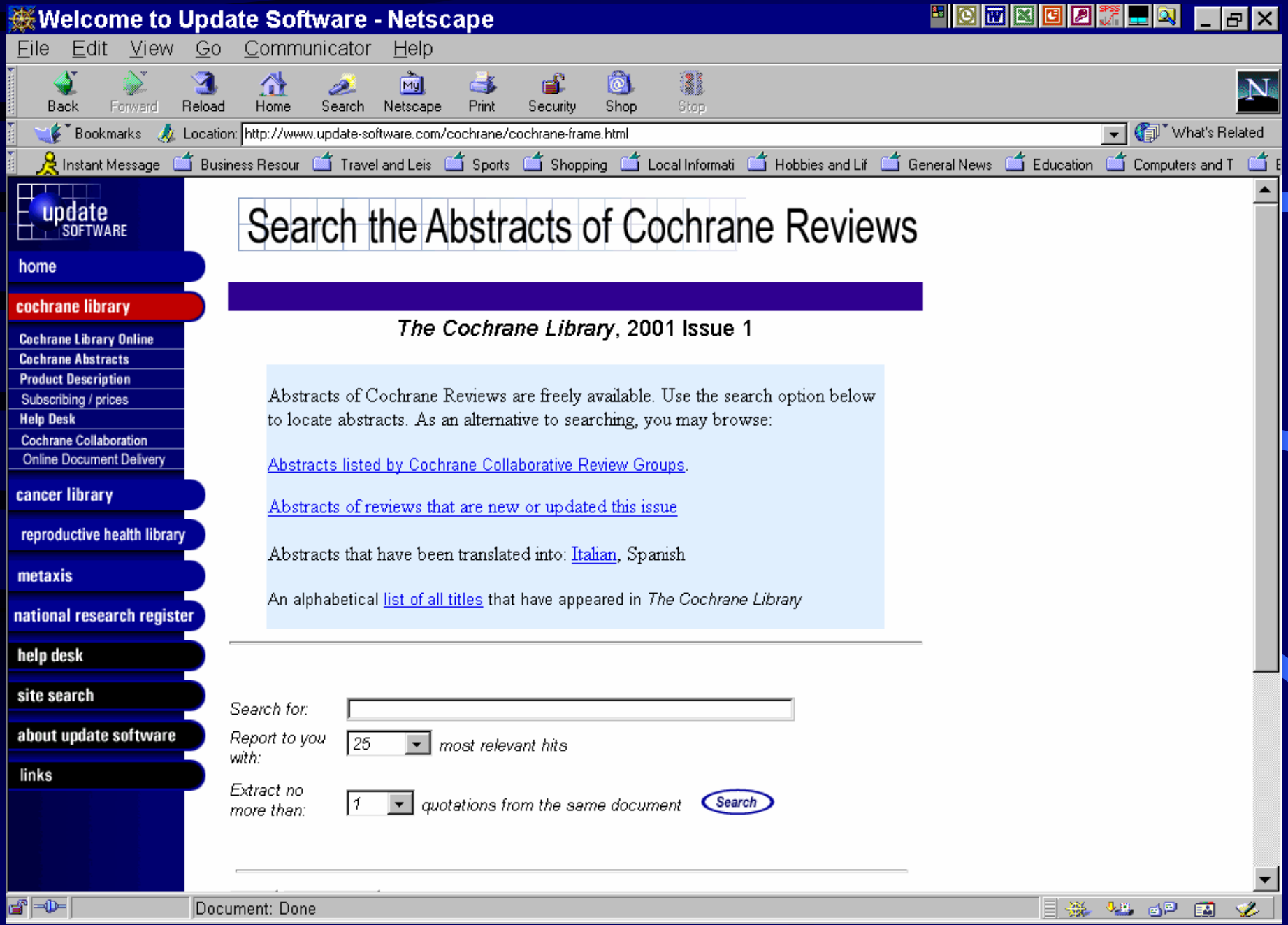
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TITLE OF THE REVIEW

SYNOPSIS PARAGRAPH(S)

ABSTRACT

Date of Review:

Background:

Objectives:

Search strategy:

Selection criteria:

Data collection and analysis:

Main results:

Reviewers' conclusions:

Citation:

EBM Websites:

- The Cochrane Library
  - $400/year for full access
  - Access to abstracts is free
  - www.cochrane.org
- Info Poems Inc/InfoRetriever
  - $149/year
  - demo - 8 time free
  - www.infopoems.com
  - InfoRetriever can be downloaded to PDA handheld such as Palm or PocketPC
  - Includes Cochran Library
- US National Guideline Clearinghouse
  - Free
  - www.guideline.gov
- DynaMed
  - Point of Care Clinical Reference
  - Free
  - www.dynamicmedical.com
- For your patients
  - Medline Plus
  - www.nlm.nih.gov/medlineplus/

Other EBM Websites:

- A physician's compilation of "just about everything" related to EBM
  - http://www.myhq.com/public/j/m/jmcnabb/
- EBM – Learning/Training Sites
  - http://www.poems.msu.edu/InfoMastery/ (InfoMastery Homepage - more about the worksheets)
  - http://cebm.jr2.ox.ac.uk/ (Sackett's Homepage)
  - http://www.shef.ac.uk/~scharr/ir/netting/ (another major EMB site from the UK)
  - http://www.med.ualberta.ca/ebm/ebm.htm (EMB Toolkit site)

Other EBM Resources:

- Surgery: basic science and clinical evidence (book/CD by: Norton, Bollinger, Chang, Lowry, Mulvihill, pass, amd Thompson) 2001

- Evidence – based surgery (book/CD by: Gordon and Cameron) 2000

“Old Guys” vs. “New Guys”

Evans 1984: The strongest predictor of knowledge of hypertension was the clinician's year of graduation.

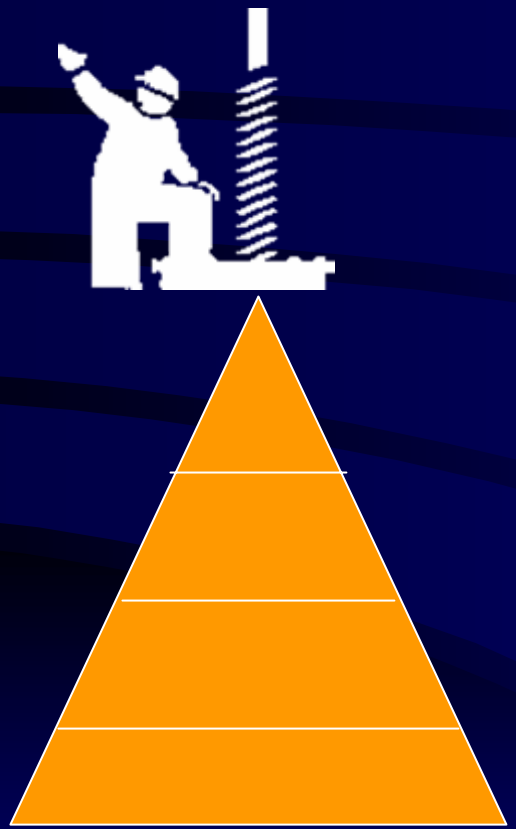
Evans et al. JAMA 1986:255:501-4

- Maximize the knowledge “inventory” with texts, notes, etc.
- “Refresh the inventory” with accurate information…EBM!

Bottom Line……..

- Be critical of what you read.
- Think about validity and reliability.
- Have the stomach to ignore bad data.
- Acknowledge that there are no definitive answers to many (or even most) of our questions.

Start at the Top and Drill Down to the Best Evidence



- POEMs
- POEs, DOEs, and Other Meta-analysis
- Other Relevant Research
- Textbooks, etc.

Why Bother?

- To understand how others are thinking.
- Example = mammography in women 40-50 years old
- If 100,000 women are screened
  - 6,034 mammograms will be abnormal
  - 5,998 (99.4%) will be false-positive
    - 36 will actually have breast cancer
      Why? = Prevalence = 0.036%

Argument = against the value of screening mammography because of false positive rates.

Great Quotes

- “Don’t confuse me with the facts, my mind’s already made up.”
- “I wouldn’t believe this crap even if it were true.”
- “It isn’t what we don’t know that gives us trouble, it’s what we know that ain’t so.”

Will Rogers

Acronyms

- SMORE: Surrogate Marker of Reliable Evidence
- PROSE: Preliminary Research on Substandard Evidence
- BOGSAT = consensus conference (“Bunch of Old Guys Sitting Around Talking”)
- YODA: Your Own Data Analysis

Levels of Evidence

I. Evidence obtained from at least one properly randomized controlled trial

II. Non – randomized studies

1. **Evidence obtained from well-designed trials without randomization**
2. **Evidence obtained from well-designed cohort or case control analytic studies, preferable from more than one research group.**
3. **Evidence obtained from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments (ie, penicillin)**

III. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Are all DOES Dispensable? POEMS vs. DOES

- Disease-free survival vs. Alive with disease
- Chemotherapy tolerance vs. drug toxicity
- Comfort/complications of NG tubes vs. benefits of NG tubes
- Anxiety of false-positive mammogram vs. detection rate for new malignancy

Types of Review Worksheets

- Treatment
- Qualitative Research
- Diagnostic Tests
- Prognosis
- Review Articles
- Practice Guidelines
- Cost Analyses
- CME/Conference Evaluation
- Pharmaceutical Representative Evaluation
- Educational Intervention