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EBM- The 5 A's

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Postgraduate EBM Coordinator, NOSM

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Disclosures and conflicts

- I am paid by NOSM to teach and oversee postgraduate EBM programs.
- I have no conflicts of interest to declare, and there is no commercial support for this talk.

Learning Objectives

At the end of the session, the participant will be able to:

- Discuss the five steps of evidence-based medicine.
- Explain two new resources or databases to enhance information-seeking skills.

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The Parachute Trial

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

BMJ 2003;327:1459–61

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Conclusions As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. WE THINK THAT EVERYONE MIGHT BENEFIT IF THE MOST RADICAL PROTAGONISTS OF EVIDENCE BASED MEDICINE ORGANISED AND PARTICIPATED IN A DOUBLE BLIND, RANDOMISED, PLACEBO CONTROLLED, CROSSOVER TRIAL OF THE PARACHUTE.

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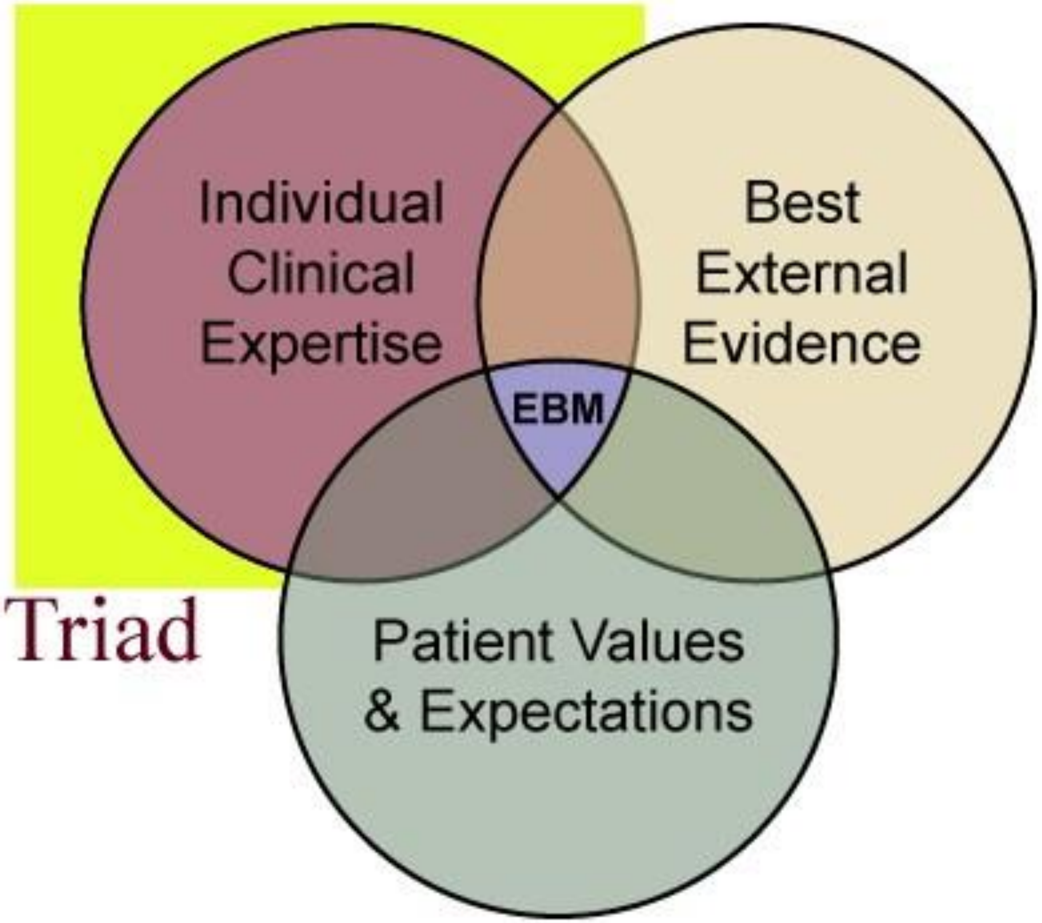
The EBM Triad



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What EBM Isn't/Is

- EBM is not about fitting the patient into the evidence or the guideline.

- It is about using the best information available to give the individual the best care we can.

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EBM

- Perhaps a better term is "evidence-informed medicine"

BMJ

BMJ 2014;348:g3725 doi: 10.1136/bmj.g3725 (Published 13 June 2014)

ANALYSIS

ESSAY

Evidence based medicine: a movement in crisis?

Trisha Greenhalgh and colleagues argue that, although evidence based medicine has had many benefits, it has also had some negative unintended consequences. They offer a preliminary agenda for the movement's renaissance, refocusing on providing useable evidence that can be combined with context and professional expertise so that individual patients get optimal treatment

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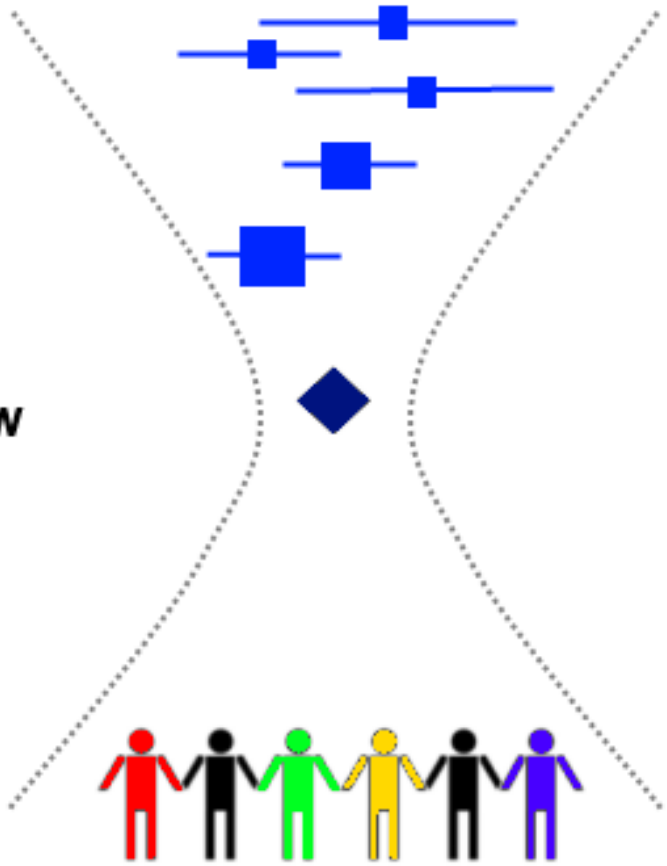
The Crisis in EBM

- EBM got hijacked
- There's too much information
- Clinical significance sometimes gets smothered by statistical significance
- Guidelines don't always fit complex real-life patients

Stage	Uncertainty
Unsynthesised trials	Moderate
Synthesis via systematic review	Low, fairly certain of the average effects of the intervention
Application to patients, in this example a NNT of 6	Moderate (at best), which of these 6 patients will gain the benefit?



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So Why Does EBM Matter?

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Truth vs. Evidence

Essay

Why Most Published Research Findings Are False

John P. A. Ioannidis

PLoS Medicine | www.plosmedicine.org 0696
August 2005 | Volume 2 | Issue 8 | e124

Table 4. PPV of Research Findings for Various Combinations of Power (1 – β), Ratio of True to Not-True Relationships *(R)*, and Bias *(u)*

1 – β	*R*	*u*	Practical Example	PPV
0.80	1:1	0.10	Adequately powered RCT with little bias and 1:1 pre-study odds	0.85
0.95	2:1	0.30	Confirmatory meta-analysis of good-quality RCTs	0.85
0.80	1:3	0.40	Meta-analysis of small inconclusive studies	0.41
0.20	1:5	0.20	Underpowered, but well-performed phase I/II RCT	0.23
0.20	1:5	0.80	Underpowered, poorly performed phase I/II RCT	0.17
0.80	1:10	0.30	Adequately powered exploratory epidemiological study	0.20
0.20	1:10	0.30	Underpowered exploratory epidemiological study	0.12
0.20	1:1,000	0.80	Discovery-oriented exploratory research with massive testing	0.0010
0.20	1:1,000	0.20	As in previous example, but with more limited bias (more standardized)	0.0015

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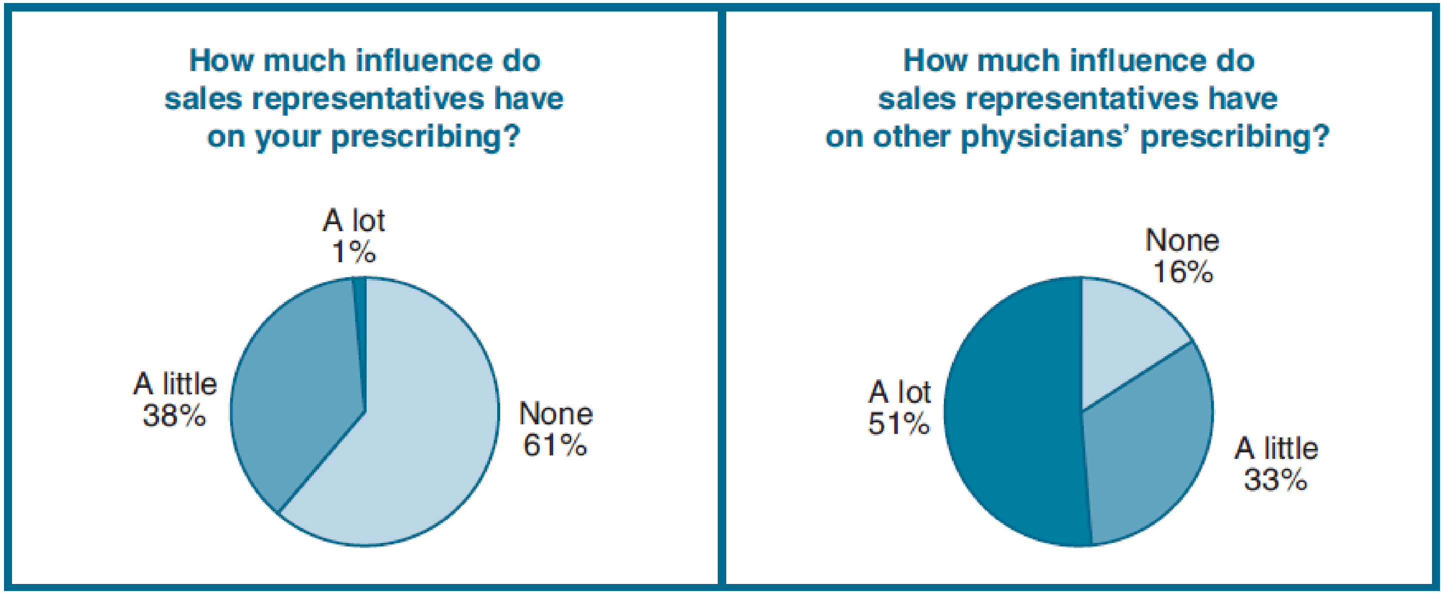
Figure 1: Survey of hospital doctors about sales representatives' influence



(Source: Steinman, 2001)

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"To keep pressing the standard EBM approach is like asking everyone who wishes to make a cake to buy the wheat to grind their own flour, refine their own sugar and extract their own flavourings before ever starting the cake. Cakes aren't made this way."

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5 A's

- Ask
- Acquire
- Appraise
- Apply
- Assess

Ask

- Sometimes we have foreground questions, and sometimes we have background questions.

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Background questions

We ask these for general knowledge about a condition or thing.

"How does heart failure cause ascites?"

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Foreground questions

Ask for specific knowledge to inform a clinical decision or action.

These can be answered using the PICO system.

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Ask

PICO

- Population
- Intervention
- Comparator
- Outcome

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Clinical Scenario

- Your 63 year old male patient comes in

"My wife saw a story on the news that Viagra causes melanoma. Since I take it twice a week, should I be seeing a dermatologist?"

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PICO

Patient's PICO

- Population- himself
- Intervention- seeing dermatologist
- Comparator- not seeing dermatologist
- Outcome- getting melanoma (or dying from melanoma-have to check with the patient)

Your PICO

You recognize that the patient's question as formulated is not currently answerable.

You need to break this question down into answerable components.

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PICO 1

- Population- middle-aged men
- Intervention- taking Viagra
- Comparator- not taking Viagra
- Outcome- getting melanoma (or dying from melanoma)

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PICO 2

If you discovered from PICO 1 that he is at higher risk, then the the next question is:

- Population- patients at increased risk for melanoma
- Intervention- screening by dermatologist
- Comparator- routine care
- Outcome- dying from melanoma

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Acquire

- Hunting vs. Foraging
- We tend to remember more from hunting, but foraging fits into our schedules better.

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ILL requests received Jul 28-Aug 4 will be handled after Aug 4. Send urgent requests by Jul 18 using RACER. ow.ly/z2KEi

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The library will be closed Tuesday, July 1st for the Canada Day holiday.

NOSM Library 16 Jun

Databases - Alphabetical Listing

Tags: databases, medline, pubmed, research, resources

Last Updated: Jul 10, 2014 | URL: http://libraryguides.nosm.ca/database | Print Guide

Databases A-B

- ACP Journal Club
  Evidence Based Medicine Reviews (OVID)
- Adverse Drug Interactions Program
  An evidence-based database of adverse drug interactions from the Medical Letter. Searches between 2 and up to 12 drugs.
- AIDSinfo
  AIDS clinical trials and drugs currently being evaluated.
- AMED (Allied and Complementary Medicine)
  A unique bibliographic database that covers a selection of journals in complementary medicine, palliative care, and several professions allied to medicine. (OVID)
- Amirsys Imaging Reference Center
  Radiology reference that offers a combination of high-quality images, classical diagnoses, and evidence-based clinical content. Includes over 72,000 x-ray, CT, MR, and ultrasound illustrations and images, plus expert, evidence-based content - including over 4,000 diagnoses - provided by imaging experts.
- BMJUpdates+
  Access to current best evidence from research to support evidence-based clinical decisions. Register for a FREE account. Produced by BMJ Publishing Group and McMaster University's Health Information Research Unit.
- Breast Cancer Searchable Information Centre
  Features a range of authoritative fact sheets, posters, and other materials from a number of government agencies including the National Cancer Institute, National Breast Cancer Coalition Fund, Centers for Disease Control and Prevention (U.S.), United States Food and Drug Administration, Office of Women's Health, and other authoritative sources.

EvidenceUpdates from BMJ

BMJ Group and McMaster University's Health Information Research Unit are collaborating to provide you with access to current best evidence from research, tailored to your own health care interests, to support evidence-based clinical decisions.

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- Links to selected evidence-based resources

Hit Parade: The most often read articles in all disciplines, in the past 30 days

1. **Treatment of Vitamin D Insufficiency in Postmenopausal Women: A Randomized Clinical Trial.**
   JAMA Intern Med *(Original)*
2. **Effect of mammographic screening from age 40 years on breast cancer mortality in the UK Age trial at 17 years` follow-up: a randomised controlled trial.**
   Lancet Oncol *(Original)*
3. **Use of drug therapy in the management of symptomatic ureteric stones in hospitalised adults: a multicentre, placebo-controlled, randomised controlled trial and cost-effectiveness analysis of a calcium channel blocker (nifedipine) and an alpha-blocker (tamsulosin) (the SUSPEND trial).**
   Health Technol Assess *(Original)*

My Hit Parade:
The most often read articles **matching your profile**, in the past 30 days.

- Clinical outcomes with beta-blockers for myocardial infarction: a meta-analysis of randomized trials.
  Am J Med. 2014 Oct;127(10):939-53. doi: 10.1016/j.amjmed.2014.05.032. Epub 2014 Jun 11. (Review)
- Do statins impair cognition? A systematic review and meta-analysis of randomized controlled trials.
  J Gen Intern Med. 2015 Mar;30(3):348-58. doi: 10.1007/s11606-014-3115-3. Epub 2015 Jan 10. (Review)
- Cannabinoids for Medical Use: A Systematic Review and Meta-analysis.
  JAMA. 2015 Jun 23-30;313(24):2456-73. doi: 10.1001/jama.2015.6358. (Review)
- Screening for Occult Cancer in Unprovoked Venous Thromboembolism.
  N Engl J Med. 2015 Aug 20;373(8):697-704. doi: 10.1056/NEJMoa1506623. Epub 2015 Jun 22. (Original)
- Air Versus Oxygen in ST-Segment-Elevation Myocardial Infarction.
  Circulation. 2015 Jun 16;131(24):2143-50. doi: 10.1161/CIRCULATIONAHA.114.014494. Epub 2015 May 22. (Original)

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BMJ McMaster PLUS

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EvidenceUpdates from BMJ

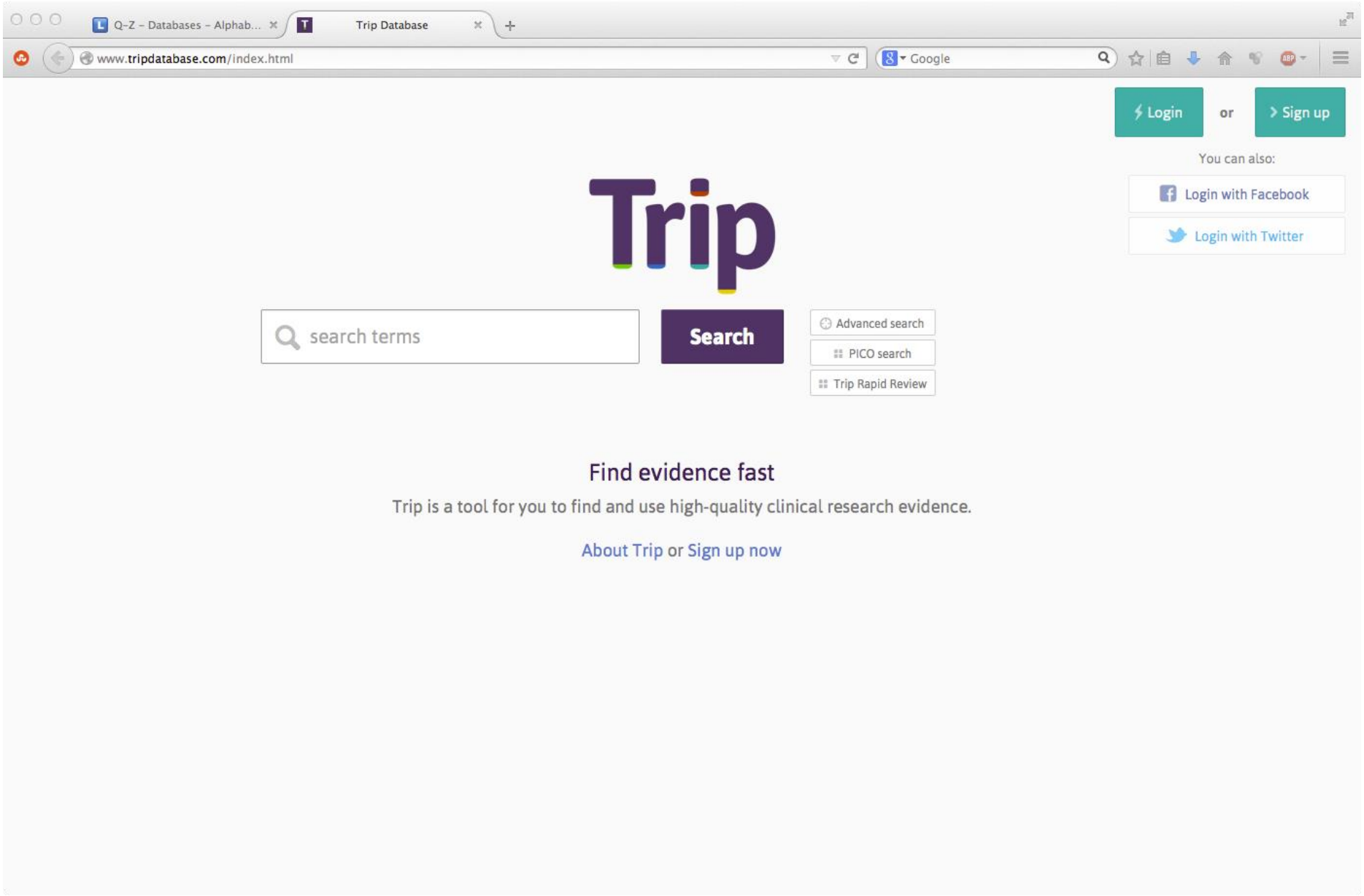
Databases - Alphabetical Listing

Tags: databases, medline, pubmed, research, resources

Last Updated: Jul 24, 2014 | URL: http://libraryguides.nosm.ca/database | Print Guide

Databases Q-Z

- Science Inventory
  Produced by the EPA, the Science Inventory is a searchable database of more than 4,000 scientific and technical work products.
- Statistics Canada
  The Canadian Government's leading resource for Canadian Statistics.
- Swine Flu Dashboard
  CABI's influenza A(H1N1) specific resources search page.
- TRIP Database
  A leading resource for Evidence-Based Medicine, allowing users to easily and rapidly identify the highest quality evidence from a wide range of sources.
- UpToDate
  UpToDate is a comprehensive evidence-based clinical information resource available to patrons on-site & off-site.
  Note Compatible with Internet Explorer versions 7-10, Chrome, Firefox, Opera & Safari.
- Web of Science
  A research platform that helps you find, analyze and share information in the sciences, social sciences, arts and humanities. You get integrated access to high quality literature through a unified platform that links a wide variety of content with one seamless search.
  Science Citation Index Expanded (1975-present)
  Social Sciences Citation Index (1975-present)
  Arts & Humanities Citation Index (1975-present)
  Conference Proceedings Citation Index- Science (1990-present)
  Conference Proceedings Citation Index- Social Science & Humanities (1990-present)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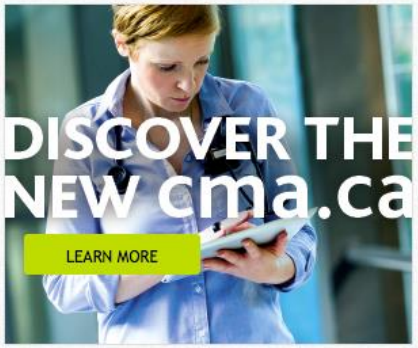

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JUL 21 CMA redesigns cma.ca with physicians' needs in mind

The Canadian Medical Association has launched a completely rebuilt cma.ca website to better serve th...

JUL 8 Court decision on refugee care applauded

The Canadian Medical Association (CMA) joined other groups in welcoming a Federal Court decision rul...

JUN 20 Canada ranks second last in comparison of health systems

The reputation of the Canadian health care system suffered collateral damage in a new Commonwealth F...

JUN 19 Health Canada seeks input on drug shortages

Health Canada is seeking input from Canadian physicians and members of the public on the current app...

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Send Comment to Editor

Community-acquired pneumonia in adults

Aztreonam	2 g IV every 6 hours
* All dosing information assumes normal renal function. Dosages may require adjustment in patients with impaired renal function. Reference - Gilbert D, Chambers H, Eliopoulos G, Saag M. The Sanford Guide to Antimicrobial Therapy. 44th ed. Sperryville, VA: Antimicrobial Therapy, Inc.; 2014.	

- see Antibiotics for adult inpatients with community-acquired pneumonia for details

Duration of antibiotic therapy:

- Infectious Diseases Society of America/American Thoracic Society (IDSA/ATS) guidelines on the management of community-acquired pneumonia in adults
  - continue antibiotic therapy for a minimum of 5 days (IDSA/ATS Moderate recommendation, Level I), until patient is both afebrile for 48–72 hours and is clinically stable (IDSA/ATS Moderate recommendation, Level II)
  - longer duration of therapy may be needed
    - if initial therapy was not active against the identified pathogen or if it was complicated by extrapulmonary infection, such as meningitis or endocarditis (IDSA/ATS Weak recommendation, Level III)
    - for patients with associated bacteremia, infection with unusual bacterial pathogens, or fungal infections
    - for patients with ventilator-associated pneumonia due to Pseudomonas; whether this can be extrapolated to community-acquired pneumonia is not clear
- **duration of 3-7 days for some antibiotics may be as effective as longer antibiotic courses for adults with mild-to-moderate community-acquired pneumonia (level 2 [likely reliable] evidence)**
  - based on systematic review limited by clinical heterogeneity
  - systematic review of 15 randomized trials of short course (7 days or less) vs. extended course (> 7 days) of antibiotic monotherapy in 2,796 patients (≥ 12 years old) with radiographically confirmed mild-to-moderate community-acquired pneumonia
  - antibiotic studied varied across trials
    - 10 trials with 1,093 patients evaluated short-course azithromycin (3 days in 6 trials, 5 days in 4 trials), of which 8 trials compared it to extended course of other macrolide
    - 2 trials with 848 patients evaluated short-course fluoroquinolones (compared to same fluoroquinolone in 1 trial, compared to amoxicillin-clavulanate in 1 trial)
    - 2 trials with 296 patients evaluated short-course beta-lactams (compared to extended course for same beta-lactams)
    - 1 trial with 559 patients evaluated short-course ketolide (telithromycin) compared to extended-course clarithromycin
  - time to outcome assessment ranged from 10 days to 42 days
  - 26.1% short-course vs. 25.6% extended-course patients failed to improve clinically in meta-analysis of 15 trials with 2,796 patients
    - not statistically significant (risk ratio 0.89, 95% CI 0.78-1.02)
    - no significant differences in subgroup analyses by class of short-course antibiotic
    - 3 trials suggested improvement with short-course antibiotic (all using azithromycin for 3 days), 12 trials suggested no differences
    - no significant differences in subgroup analysis of 8 higher-quality trials
  - no significant differences in overall mortality
    - 7 trials had no deaths
    - overall mortality rate 1.7%, range 0.9% to 6.7% in trials with deaths
    - risk ratio 0.81 (95% CI 0.46-1.43) in meta-analysis of 8 trials reporting deaths
  - Reference - Am J Med 2007 Sep;120(9):783, commentary can be found in J Fam Pract 2007 Dec;56(12):1003 **EBSCOhost Full Text**
  - *DynaMed commentary* -- most trials evaluating 3 day duration used azithromycin, which has a prolonged half-life, with therapeutic tissue concentrations maintained for extended periods beyond last dose. This may have skewed results to favor shorter courses overall. (Infect Control Hosp Epidemiol 1992 Jun;13(6):357)

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Table 3. Rank ordering of the 10 evaluated online texts

Text	Timeliness	Breadth	Quality
DynaMed	1	3	2
UpToDate	5	1	2
Micromedex	2	8	2
Best Practice	3	4	7
Essential Evidence Plus	7	7	2
First Consult	9	5	2
Medscape Reference	6	2	9
Clinical Evidence	8	10	1
ACP PIER	4	9	7
PEPID	N/A	6	10

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Good from bad summaries

- "To judge the strength of the commitment to evidence to support inference, check whether you can distinguish statements that are based on high-quality vs. low-quality evidence. If you cannot make this distinction, dismiss the resource altogether."

Gordon Guyatt

Appraise


Professional & Technical › Medical › James McCormack
How to CRITICALLY APPRAISE an RCT in 10 minutes
James McCormack
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No Customer Ratings
Published Jul 4, 2012
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This book includes video.
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How to Critically Appraise an RCT In 10 Minutes
James McCormack ›
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If the thought of reviewing a clinical study seems like an insurmountable task, this book was developed to show you how to critically evaluate a randomized controlled trial in around 10 minutes.
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(yes I know there are more than six steps in the picture)

1) First you have to figure out your NEEDS

2) Second, you have be able to SEARCH for BIAS

3) Third, you have to IGNORE much of the text

4) Fourth, find out WHO was studied

5) Fifth, find out WHAT HAPPENED to them

6) Finally, determine if you should CARE about the results

Clin Orthop Relat Res (2015) 473:198–203
DOI 10.1007/s11999-014-3722-7

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SYMPOSIUM: 2014 KNEE SOCIETY PROCEEDINGS

The Alpha-defensin Test for Periprosthetic Joint Infection Outperforms the Leukocyte Esterase Test Strip

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Published online: 19 June 2014

Abstract

Background Synovial fluid biomarkers have demonstrated diagnostic accuracy surpassing the currently used diagnostic tests for periprosthetic joint infection (PJI).

Questions/purposes The purpose of this study is to directly compare the sensitivity and specificity of the synovial fluid α-defensin immunoassay to the leukocyte esterase (LE) colorimetric test strip.

Methods Synovial fluid was collected from 46 patients meeting the inclusion criteria of this prospective diagnostic study. Synovial fluid samples were tested with both a novel synovial-fluid-optimized immunoassay for α-defensin and the LE colorimetric test strip. The Musculoskeletal Infection Society (MSIS) definition was used to classify 23 periprosthetic infections and 23 aseptic failures; this classification was used as the standard against which the two diagnostic tests were compared.

Results The synovial fluid α-defensin immunoassay correctly predicted the MSIS classification of all patients in the study, demonstrating a sensitivity and specificity of 100% for the diagnosis of PJI. The α-defensin assay could be read for all samples, including those with blood in the synovial fluid. The leukocyte esterase test strip could not be interpreted in eight of 46 samples (17%) as a result of blood interference. Analysis of the LE strips that could be interpreted yielded a sensitivity of 69% and a specificity of 100%.

The institution of one or more of the authors (CD, JP) has received, during the study period, funding from CD Diagnostics (Wynnewood, PA, USA) and Zimmer (Warsaw, IL, USA). Several of the authors certify that they (KK, PK, AC, KS, REB, JP), or a member of his or her immediate family, has received or may receive payments or benefits, during the study period, an amount of USD 10,000 to USD 100,000 from CD Diagnostics. One of the authors certifies that he (CD), or a member of his or her immediate family, has received or may receive payments or benefits, during the study period, an amount of more than USD 1,000,001 from CD Diagnostics. One of the authors certifies that he (JP), or a member of his or her immediate family, has received or may receive payments or benefits, during the study period, an amount of USD 100,001 to USD 1,000,000 from Zimmer. One of the authors certifies that he (CD), or a member of his or her immediate family, has received or may receive payments or benefits, during the study period, an amount of USD 10,000 to USD 100,000 from Zimmer.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at CD Diagnostics, Wynnewood, PA, USA, and the Rothman Institute, Philadelphia, PA, USA.

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 26, 2015 VOL. 372 NO. 9

Randomized Trial of Peanut Consumption in Infants at Risk for Peanut Allergy

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ABSTRACT

BACKGROUND

The prevalence of peanut allergy among children in Western countries has doubled in the past 10 years, and peanut allergy is becoming apparent in Africa and Asia. We evaluated strategies of peanut consumption and avoidance to determine which strategy is most effective in preventing the development of peanut allergy in infants at high risk for the allergy.

METHODS

We randomly assigned 640 infants with severe eczema, egg allergy, or both to consume or avoid peanuts until 60 months of age. Participants, who were at least 4 months but younger than 11 months of age at randomization, were assigned to separate study cohorts on the basis of preexisting sensitivity to peanut extract, which was determined with the use of a skin-prick test — one consisting of participants with no measurable wheal after testing and the other consisting of those with a wheal measuring 1 to 4 mm in diameter. The primary outcome, which was assessed independently in each cohort, was the proportion of participants with peanut allergy at 60 months of age.

RESULTS

Among the 530 infants in the intention-to-treat population who initially had negative results on the skin-prick test, the prevalence of peanut allergy at 60 months of age was 13.7% in the avoidance group and 1.9% in the consumption group ($P<0.001$). Among the 98 participants in the intention-to-treat population who initially had positive test results, the prevalence of peanut allergy was 35.3% in the avoidance group and 10.6% in the consumption group ($P=0.004$). There was no significant between-group difference in the incidence of serious adverse events. Increases in levels of peanut-specific IgG4 antibody occurred predominantly in the consumption group; a greater percentage of participants in the avoidance group had elevated titers of peanut-specific IgE antibody. A larger wheal on the skin-prick test and a lower ratio of peanut-specific IgG4:IgE were associated with peanut allergy.

CONCLUSIONS

The early introduction of peanuts significantly decreased the frequency of the development of peanut allergy among children at high risk for this allergy and modulated immune responses to peanuts. (Funded by the National Institute of Allergy and Infectious Diseases and others; ClinicalTrials.gov number, NCT00329784.)

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*A complete list of members of the Learning Early about Peanut Allergy (LEAP) Study Team is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on February 23, 2015, at NEJM.org.

N Engl J Med 2015;372:803-13.
DOI: 10.1056/NEJMoa1414850

The content of this article is the sole responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Supported by grants from the National Institute of Allergy and Infectious Diseases (NO1-AI-15416, UM1AI109565, and HHSN272200800029C); Food Allergy Research and Education; the Medical Research Council and Asthma UK; the United Kingdom Department of Health, through a National Institute for Health Research comprehensive Biomedical Research Center award to Guy's and St. Thomas's NHS Foundation Trust, in partnership with King's College London and King's College Hospital NHS Foundation Trust; the National Peanut Board; and the United Kingdom Food Standards Agency.

Dr. Brough reports receiving grant support from Action Medical Research and study materials from Stallergenes, Thermo Scientific, and Meridian Foods. Dr. Lack reports holding stock and stock options in DBV Technologies. No other potential conflict of interest relevant to this article was reported.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank Daniel Rotrosen, Alkis Togias, and Gerald Nepom for their input on reviewing the manuscript; Stephen Durham, Andrew Saxon, David Broide, and Jeffrey Bluestone for their contributions to the study design; the many nurses, dietitians, doctors, and members of the administrative staff at St. Thomas' Hospital Children's Allergy Service for clinical and logistic assistance; Poling Lau for administrative support in the preparation of the manuscript; many other colleagues for their generous cooperation and help in recruitment for the study; Herman Mitchell, Samuel Arbes, and Kristen Much for statistical support; Jeremy Wildfire, Nathan Bryant, and Ryan Bailey for help with graphics; Isaac Kaye for facilitating our collaborations with Israeli colleagues; Yael Friedman and Dr. Yitzhak Katz for their observations on peanut consumption in Israeli infants; Drs. Tom Marrs and Michael Perkin for assistance with medical coverage; Dr. Kirsty Logan for project-management coverage; and all the children and their families who took part in the study.

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Apply

- AKA Knowledge translation.
- This is often a weak link in the EBM chain.
- Ultimately there's little point in the first three steps if you're not going to apply it to the individual patient.

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Assess

- Did the intervention have the intended consequences?
- Consider d-Dimer, pediatric head CT rules.

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Conclusion

- EBM has gotten a bum rap.
- It is not about guidelines or cookbook medicine, or making clinicians feel stupid.
- It is a skill set designed to help us get the best information, which we can then combine with our clinical expertise and patient values to arrive at the best options for our individual patients.

Conclusion

This skill set revolves around the 5 A's:

- Ask
- Acquire
- Appraise
- Apply
- Assess

Five things to try after this session

- Go to the NOSM library and check out TRIP and BMJ+
- Register at the CMA website, then try Dynamed and Poems
- Think about the question you want answered, not the answer the author is giving you (PICO)
- Each week, write down two clinical questions that have come up, then set aside a little bit of time to find the answers
- When reading an article, check the little print for signs of bias

Questions?