



Evidence Based-Medicine: A Case Study of Vaccines and Autism

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Overview of Today's Lecture





- Leah: Introduction to Evidence-based medicine
- Johnny: Vaccines and Public Health
- Alison: Autism and Vaccines Case Study



Where do you obtain medical advice?





What is evidence-based medicine (EBM)?

• "the conscientious, explicit, and judicious use of current best evidence in making decisions about individual patients." David Sackett, 1996.





Evidence Based Medicine Throughout History

• Bloodletting: withdrawing blood to treat disease, common for 2,000 years until 1800s



Pierre Louis' Bloodletting data, 1850

	Died	Total	Mortality (%)
Bled early	18	41	44%
Bled late	9	36	25%
Overall	27	77	35%



Evidence Based Medicine Throughout History

- Scurvy: vitamin C deficiency characterized by bleeding gums, loss of teeth, spotty skin
- Anecdotal evidence since 1500s for use of lemons and limes to treat scurvy



Addition to Diet	Observed Effect	
Quart of cider	Minor improvement	
Unspecified elixir	No change	
Sea water	No change	
Garlic, mustard, horseradish	No change	
Vinegar	No change	
2 oranges and 1 lemon	Major improvement!	

James Lind's Randomized Controlled Trial, 1747



Modern Examples of Evidence Based Medicine

- Does a treatment work?
 - Antibiotics are successful at treating bacterial infections, but not viral infections
 - Beta blockers lower the risk of a heart attack
- Is the treatment appropriate?
 - <u>Overuse</u>: 50-80% of patients with upper respiratory tract infections (like a cold) are prescribed antibiotics
 - <u>Underuse</u>: Beta blockers are prescribed to as few as 40% of eligible heart disease patients









Modern Examples of Evidence Based Medicine

- What population should use a treatment?
 - <u>Men</u>: Aspirin is successful at reducing heart attack rates but not stroke rates
 - <u>Women</u>: Aspirin is successful at reducing stroke rates but not heart attack rates





Who participates in EBM?



http://cdc.gov/ncbddd/autism/screening.html, http://www.whitehouse.gov/our-government/legislative-branch http://farm1.static.flickr.com/42/74267002_dad8d73208_o.jpg, http://commons.wikimedia.org/wiki/File:75francis180.jpg



How to collect Evidence?

- Observational Studies
 - Retrospective (back in time)
 - Prospective (forward in time)
- Experimental Studies
 - Randomized Controlled Trial

Experimental Studies more directly test a causal relationship between treatment and outcome



Hormone Replacement Therapy

- Treatment to relieve the symptoms of menopause caused by decreasing hormone levels
- Pill, patch, or cream containing estrogens and/or progesterone





Observational Study: Retrospective



Stampfer M., et al. Int Jour Epid 2004; 33:445-53



Observational Study: Prospective





Experimental Study: Randomized Controlled Trials

Women's Health Initiative, drug effectiveness trials

Population:



Rossouw JE et al., JAMA 2002 July 17; 288(3): 321-33



Experimental Study: Randomized Controlled Trials

Women's Health Initiative, drug effectiveness trials

Randomization:





Rossouw JE et al., JAMA 2002 July 17; 288(3): 321-33

Experimental Study: Randomized Controlled Trials



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Rossouw JE et al., JAMA 2002 July 17; 288(3): 321-33

Bias and Confounders

• Differences in socioeconomic status, diet and exercise





DA drug/ vaccine approval process

How New Drugs Are Approved Today





Drug development: Costs and Time

Up to 12-15 years from preclinical studies to approved drug

\$800 million to \$2 billion to bring new drug to market



Clinical Trial Ethics

• How to protect study participants and ensure valid results

Potential Problem	Solution
Tests and procedures may unnecessarily hurt patients	Institutional Review Board must approve research plans
Patients may be coerced or misinformed about risks	Study participants must sign informed consent documents
Researchers may be biased or have financial stake in results	Researchers must disclose their conflicts of interest



Limitations of Evidence-Based Medicine

- Randomized Trials are not always ethical or applicable
- Does not replace the doctor-patient relationship



- Does not account for individual genetic or environmental differences
- Doctor recommendations and insurance coverage may differ



Evidence-Based Medicine: Summary

- Evidence-based medicine combines clinical expertise with scientifically sound research
- Observational and experimental studies are used to assess disease risks and treatment effectiveness
- Drug development requires clinical trials, time, money, and ethical considerations
- Next: applying evidence-based medicine to vaccines



