

Chapter 10  
Evaluating Health Claims in Alt-Med

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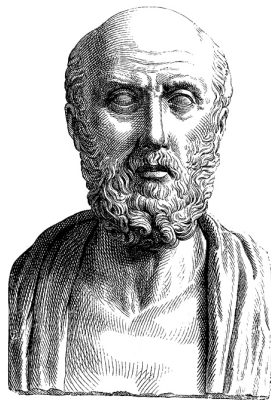
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There are in fact  
two things, science  
and opinion;  
the former begets  
knowledge, the  
latter ignorance.

Hippocrates of Kos



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A Big Chunk of Change

- In the U.S. approximately \$3 *trillion* are spent on healthcare each year, or \$10,000 per person
- Other countries worldwide often spend up to 10% of their GDP on healthcare
- We should know if it's being spent wisely or poorly



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### Operational Definitions

- Alternative and complementary medicine are “health care approaches developed outside of mainstream Western, or conventional, medicine”
- Integrative health care describes “conventional and complementary approaches together in a coordinated way”

(NCCIH, n.d.)

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### Operational Definitions

- Evidence-based practice is
  - “...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”
  - “...healthcare practice that is based on integrating knowledge gained from the best available research evidence, clinical expertise, and patients’ values and circumstances.”

(Sackett et al., 1996)  
(Dickersin et al., 2007)

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### Evidence-based Practice

- Uses those medicines, therapies, or diagnostic assessments that have been demonstrated to be effective via well-controlled trials
- A new term with a long history, including large amount of push back from physicians of times past (and even currently)

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### EBP vs. CAM

- EBP is a method of making decisions, while CAM refers to a type of treatment
- EBP starts with the patient and asks what is the best evidence to achieve an outcome
- In EBP, there is not “alternative” or “conventional” treatments, but...

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### Levels of Evidence

- Evidence-based treatments
- Poorly studies treatments
- Non-evidence-based treatments

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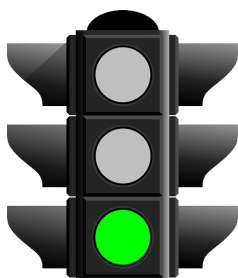
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### Evidence-Based Treatments

- Those procedures, medications, and the like which have been reliably shown to cause improvement in various symptoms



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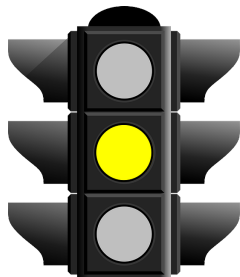
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### Poorly Studied Treatments

- Those procedures, medications, and the like which have not been studied well enough to determine their impact on various symptoms, or for which there is conflicting evidence regarding their effectiveness




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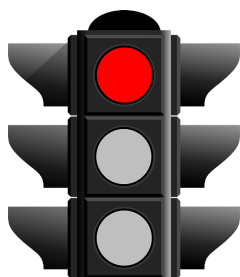
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### Non-Evidence-Based Treatments

- Those procedures, medications, and the like which have been reliably shown *not* to cause improvement in various symptoms




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### No Panaceas

- No treatments will cure all disease or illness
- The same treatment can be EBT for one problem, but non-EBT or PST for another
- E.g., antibiotics are EBT for bacterial infections, but non-EBTs for viral ones

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### Non-Static Categories

- As in all science, our understanding of health treatments is constantly evolving
- This means that treatments can move from “mainstream” to “alternative” *and vice versa*
  - Various herbal supplements
  - Deep breathing

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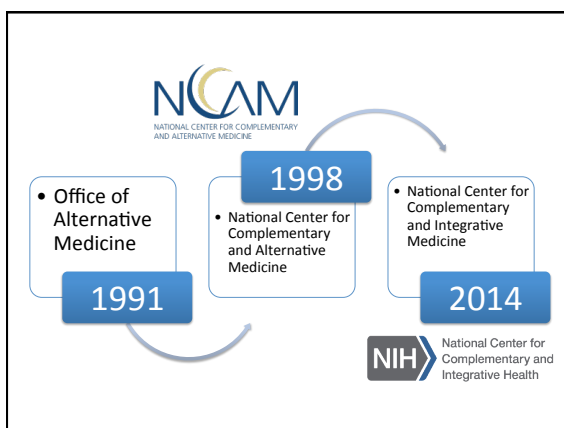
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### Why the Change?

- “True alternative medicine is uncommon. Most people who use non-mainstream approaches use them along with conventional treatments.”
- The name shifts seem designed to help obscure some points, though

(NCCIH, n.d.)

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### Purposeful Confusion?

- There are increasingly negative connotations for the term “alternative med” among many
- The NCCIH also describes numerous treatments that are non-EBT as being either EBT or PST
  - Homeopathy, acupuncture

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### Purposeful Confusion?

- Currently, the NCCIH puts CAM into three groups
  1. Natural products
    - Herbs, vitamins, minerals, probiotics, and other dietary supplements
  2. Mind and body practices
    - Yoga, chiropractic manipulation, massage, meditation, acupuncture, relaxation, hypnotherapy, movement therapies
  3. Other complementary health approaches
    - Naturopathy, homeopathy, traditional Chinese medicine, Ayurvedic medicine, and anything else that doesn't fit in the above two categories

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### Purposeful Confusion?

- This grouping obscures that each category contains a mixture of treatments with very differing LoE
- Well-supported EBTs (relaxation) are mixed with non-EBTs (acupuncture) and PSTs (probiotics)

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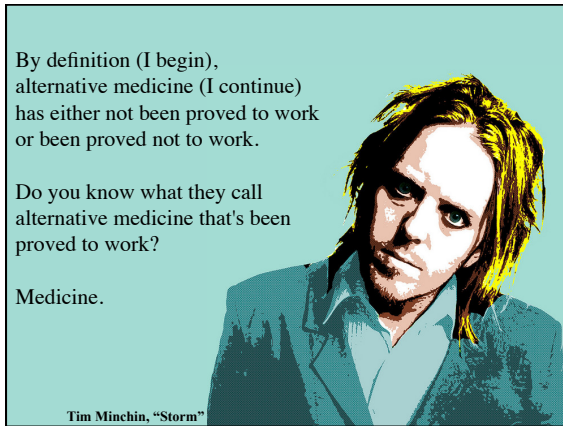
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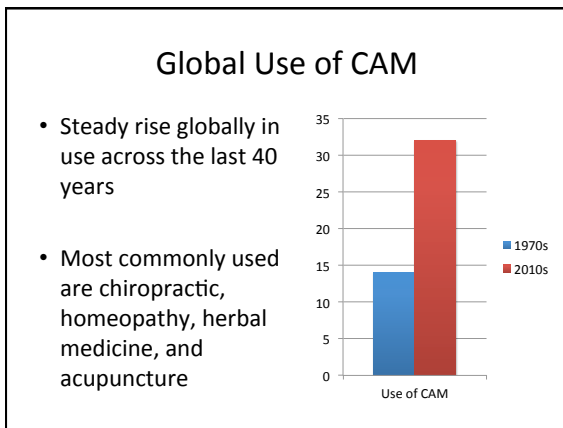
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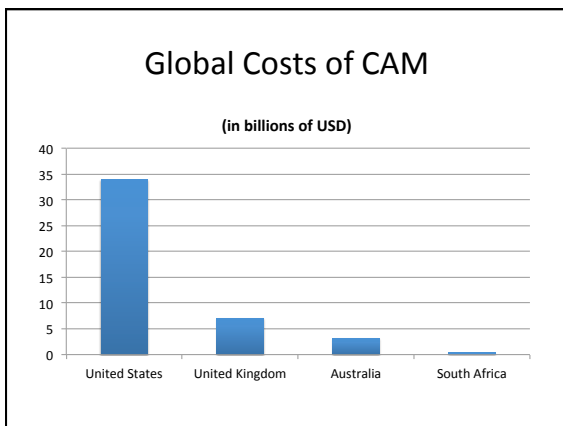
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Why would people spend so much money  
on things that don't work?

Wouldn't they realize these treatments were  
ineffectual and turn to something else for help?

The answer is **"Because they do work, just not  
for the reasons people think they do."**

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### Importance of Research

- Healthcare providers who use EBT rely heavily  
on valid and reliable research studies
- Such research is critical because of
  - a) how easily bias can creep into our everyday  
decision making
  - b) how influenced we are by powerful social forces,  
such as advertising
  - c) the strength of the **placebo effect**

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### The Placebo Effect

- People's beliefs have a powerful impact not  
only on how they process information, but  
also on their body
- A *placebo* is any type of sham or inactive  
medical treatment or procedure
  - Sugar pills
  - Fake infusions
  - Fake surgeries

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## The Placebo Effect

- "...the measurable, observable, or felt improvement in health or behavior not attributable to a medication or invasive treatment that has been administered."
- In other words, someone gets a placebo and then shows improvement, *even with no active treatment*

(Carroll, 2015)

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## "I will please"

- Decades of research have shown how powerful the placebo effect can be
- Better in subjective, as opposed to objective, tests
  - People with asthma report feeling better with sham inhalers, even though there is not a measurable change in lung functioning

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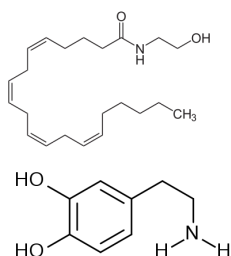
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## Biology & the Placebo

- Taking a placebo can cause
  - Production of cannabinoids and opioids
  - Release of dopamine
  - Increased prefrontal cortex activation




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### Psychology & the Placebo

- Expectations color our perception of both how we feel and how we behave
- Even when given non-alcoholic beer, people feel and act as if they are intoxicated, as long as they were told it was alcoholic




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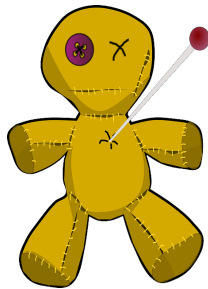
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### Nocebo Effect

- When something negative happens or you feel worse after receiving a sham treatment because you expect to feel worse




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### How to Make a Placebo Stronger

- Be friendly, comforting, and interested
- Injection works better than a capsule, which works better than a pill
- Be more expensive and in fancy packaging

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### Regression to the Mean

- RTM is a major issue we face in healthcare research
- When you measure something which has moved in an extreme direction, it will most likely move back (regress) towards normal (the mean) across repeated measurements

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### RTM Example

1. You begin to develop a headache
2. It starts small (not far from the “no headache” mean)
3. It builds over time, becoming unbearable (an extreme value from the mean)
4. You take an aspirin 
5. Soon, your headache is decreased (RTM)

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### RTM Example

- Three possible reasons why your headache went away
  - Aspirin truly worked to decrease pain
  - Aspirin had a placebo effect
  - Pain may have decreased naturally regardless of what you did (RTM)
- Each is possible and plausible, which is why we need well-controlled research to sort it out

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### “Does this treatment work?”

- Instead of that, we have to ask both:
  1. “Does this treatment work better than a placebo?”
  2. “Would this condition naturally improve over time, even with no intervention?”

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### The Blind Researching the Blind

- The best way to conduct research on treatment outcomes is through the use of randomized, placebo-controlled, double-blind procedures (RPCDB)
- These types of high quality clinical trials are what need to be relied on, in order to determine if something is an EBT

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### RPCDB in Action

1. Divide the entire group of people in the study randomly into the treatment and control arms
2. Compare the treatment to a matched type of placebo, rather than nothing
3. Participants should not know what treatment arm they are in (being *blinded*)
4. The researchers should also not know what arm a participant is (being *double-blinded*)

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### The Gold Standard

- This type of trial is critical, as it controls for bias and placebos
- Studies that don't meet these criteria can show treatments to work, when they actually don't




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### Why is CAM So Popular?

- Huge numbers of people spend huge amounts of money each year on CAM, even though most is non-EBT
- Exact reasons differ based on the individual, but here are some of the most commonly seen reasons

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### Why is CAM So Popular?

- No surgery, no "drugs"
- They are seen as "natural"
- Many are cheaper and easier to access
- Reaction to the failings of conventional med

(Carroll, 2003)

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### Why is CAM So Popular?

- Political lobbying and the air of approval via state licensure
- Misunderstanding of how science self-corrects across time
- It works, thanks to placebo effects!

(Carroll, 2003)

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### Tips for Avoiding Non-EBT

- The product is advertised as a quick and effective cure-all for a wide range of ailments
- The promoters use words like scientific breakthrough, miraculous cure, exclusive product, secret ingredient, or ancient remedy
- The text is written in "medicalese"

(FTC, 1999)

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### Tips for Avoiding Non-EBT

- The promoter claims the government, the medical profession, or research scientists have conspired to suppress the product.
- The advertisement includes undocumented case histories claiming amazing results.
- The product is advertised as available from only one source.

(FTC, 1999)

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### Typical CAM User

- Middle-aged, female, and of higher than average education and income
- Likely to have multiple medical conditions, especially ones conventional medicine often fails at treating
- Desperate for help and relief, willing to try anything

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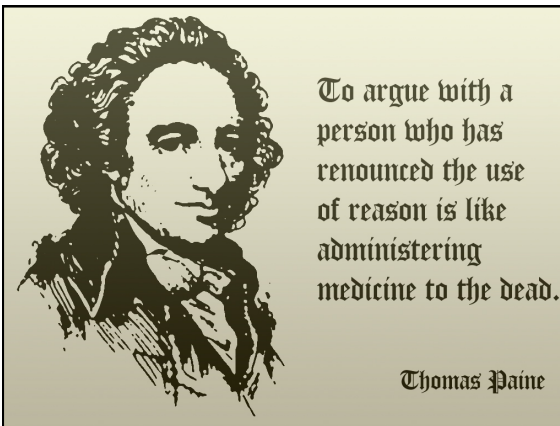
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