## **Belief in theories**

From: Key Concepts for assessing claims about treatment effects and making well-informed treatment choices (Version 2022)

1.2a Do not assume that a plausible explanation of how or why a treatment might work is a sufficient basis for a claim about treatment effects.

# **Explanation**

Treatments that should work in <u>theory</u> often do not work in practice, or may turn out to be harmful. A plausible explanation of how or why a treatment might work does not prove that it actually does work, or that it is safe. For example, cutting someone to make them bleed (bloodletting) used to be a common treatment for lots of problems. People believed it would rid the body of "bad humours", which is what they thought made people sick. But bloodletting did not help. It even killed people, including George Washington, the first president of the United States [Morens 1999]. His doctors drained 40% of his blood to treat a sore throat!

A more recent theory was that operating on blocked tubes (arteries) that carry blood to the brain would stop damage to the brain (strokes). That makes sense, but when that theory was tested in a fair comparison, researchers found not only that it did not help, but that some people died from the surgery [Powers 2011 (RS)].

Even if there is plausible evidence that a treatment works in ways likely to be beneficial, the size of any such treatment effect, and its safety, cannot be predicted. For example, most drugs in a class of heart medicines called beta-blockers have beneficial effects in reducing recurrence of heart attacks; but two drugs in the class – pronethalol and practolol – were taken off the market because of unanticipated side effects [Furberg 1999]. Similarly, it cannot be assumed that a treatment works or does not work based on the type of treatment. For example, it cannot be assumed that all complementary medicines or that all modern medicines do or do not work, or that all vaccines do or do not work. On the other hand, not understanding how a treatment works does not mean that it does not work.

# Basis for this concept

Protocols for randomized trials of new treatments almost always have a rationale that includes an explanation of how or why the treatment might work. A systematic review of four cohorts of randomized trials including 743 trials involving almost 300,000 patients found that only slightly more than half of the new treatments were better than established treatments and few were substantially better, despite plausible explanations why they might be better [Djulbegovic 2012 (SR)].

New medicines are developed based on an understanding of how and why they are expected to work, and many medicines do, in fact work. However, among 222 novel medicines that were found to be effective and were approved by the U.S. Federal Drug Administration (FDA) from 2001 to 2010, about one-fifth were found to have unanticipated serious adverse events after they had been approved [Downing 2017 (RS)].

Homeopathy has been used for over 200 years, based on the theory that patients with signs and symptoms can be helped by a homeopathic remedy that produces those signs and symptoms in healthy individuals, and that homeopathic remedies retain biological activity after repeated dilution.

But systematic reviews of the effects of homeopathy have found no condition that responds convincingly better to homeopathic treatment than placebo [Ernst 2002 (SR), Jorgensen 2013 (SR)].

It is argued that the use of theory will lead to more effective behaviour change interventions. However, there are dozens of different theories to choose from [Davis 2015 (SR)]. Interventions to change health-related behaviours typically have modest effects, and systematic reviews of randomized trials of health behaviour change interventions have not found theory-based interventions to be more effective than non-theory-based interventions [Dalgetty 2019 (SR)].

# **Implications**

Do not assume that claims about the effects of treatments based on an explanation of how they might work are correct if the treatments have not been assessed in systematic reviews of fair comparisons of treatments.

### References

#### Systematic reviews

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#### **Research studies**

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