

The weight of evidence

Is there any other way to evaluate whether a new treatment constitutes a therapeutic advance than to look for evidence that it is more effective than existing treatments, has fewer or less severe adverse effects, or is easier to use?

When confronted with an array of evidence, how much weight should be given to each piece of evidence? And at what point can this evidence be considered sufficiently strong to support the evaluator's decision?

Can the decision rest on the opinion of a single person, even an expert on the subject? Or should we give priority to more robust evidence?

Since the late 20th century, it has been common practice in the field of healthcare to grade the quality of evidence, and to consider that well-conducted double-blind randomised comparative clinical trials provide the highest level of evidence. Far higher than experts' opinions and higher too than other types of study, such as cohort studies, in which events are counted in groups of people that are so different that it is impossible to be sure that only the treatment under evaluation is responsible for any difference observed.

But does a single comparative trial carry so much weight as to systematically sway the evaluator's decision-making process more than all other forms of evidence?

In the pharmaceutical field, marketing authorisations are frequently granted on the basis of a single trial. This trial will often only have compared the drug with placebo, even when other treatment options already exist. Some drug regulatory agencies consider such evidence sufficient for granting marketing authorisation. Yet this evidence is often too weak to be able to conclude that the drug constitutes a tangible therapeutic advance.

Prescrire's approach is to take into account consistent bodies of evidence, by weighing all the available data, over time, objectively and with a completely open mind. In some cases this means that a large body of lower-level evidence carries more weight than a single comparative trial. For example, Prescrire qualified its proposals on the place of certain anticoagulants in the treatment of atrial fibrillation on the basis of evidence from cohort studies that included tens of thousands of patients (see pp. 159-160 of this issue).

The reason is that randomised trials are not always the most relevant source of data when conducting a thorough evaluation of a drug's adverse effects rather than just its efficacy. In such cases, evidence that is considered to carry less weight when evaluating efficacy will sometimes carry more weight, and may even suffice when the goal is to first do no harm.

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