

# INTERPRETING

Randomised controlled trials can be approached from four viewpoints. Understanding these

No doctor can seriously be against evidence based medicine, as described by Sackett and colleagues.<sup>w1</sup> The idea of resorting to “prejudice” or any form of non-evidence based medicine is absurd.<sup>w2</sup> And yet there are problems with evidence based medicine.<sup>w3 w4</sup> These problems are with interpretation<sup>w5 w6</sup> and with implementation<sup>w7 w8</sup> of evidence. These problems are not unique to evidence based medicine; they are found in many other situations in which evidence needs interpretation.

The problems of interpretation are present at the level of doctors understanding evidence themselves.<sup>w9</sup> They are magnified when doctors try to present data about risks to patients in understandable formats.<sup>w10 w11</sup> The third layer of complexity comes when we try to understand how patients make sense of the information presented to them.<sup>w12</sup>

We are under a duty to respect the autonomy of patients<sup>w13</sup> and to try to present the “facts” to them in a neutral unbiased way so that they can make their own well informed decisions about the likely risks and benefits of treatment.<sup>w14</sup> The difficulty in this is partly that evidence of itself does not show anything. The other difficulty is that evidence may show multiple things, and these only become apparent when considering the different ways that evidence is presented.

## Ways of presenting evidence

The west of Scotland coronary prevention study (WOSCOPS) is an important study that provides evidence about the efficacy of reducing lipids for the primary prevention of coronary heart disease.<sup>w15</sup> I can present the evidence to a colleague or to a patient in one of several ways<sup>w6 w9</sup> depending on how I want you, or a patient, to regard the results. Each of the four commonly used quantities would be honest, accurate, and consistent with the medical evidence, but each represents only part of the truth.

I could use the relative risk reduction (RRR) and say to a patient that I could reduce his or her future risk of a heart attack or stroke by 31%. This sounds impressive and might well be sufficiently persuasive that the patient would accept “31% off” and think it was a good deal.

What I would miss in this presentation is that I would not say 31% of what. So I could move to an absolute risk reduction (ARR) and explain that to the patient. So I could say, “With this drug 98.8% of patients will still be alive after 4.9 years whereas of those who don’t take the drug 98.3% will still be alive. Your chances of being alive are better on this drug.”

I could convert this ARR to a number needed to treat (NNT). From WOSCOPS this reduction in event rate comes out as 111 need to take this drug every day for 4.9 years to prevent one death.<sup>w6</sup> No one



knows which of these men is the one whose life has been saved.

I could convert this to a statement of the patient’s personal probability of benefit (PPB).<sup>w10</sup> This figure answers the patient’s question, “What’s in this treatment for me?” From the number needed to treat above for pravastatin for primary prevention of coronary heart disease the personal probability of benefit from treatment is less than 1% a year.

## Perspectives on the data

Each of these four quantities is either explicit or embedded in the WOSCOPS data. They give different viewpoints on the data.

### Area-wide

The RRR gives a broad, area-wide perspective. From the point of view of a public health doctor surveying the health of an area or a cardiologist managing the local coronary care unit, a 30% reduction in the number of people who have heart attacks a year is a big public health gain and probably a reduction in hospitals’ acute workload. From this viewpoint, it would seem that anyone against use of pravastatin as described in WOSCOPS is misguided.

### Necessary workload

The ARR and its counterpart the NNT measure the size of the workload needed to be done to achieve the public health gains. They do not measure the acute events prevented (which as non-events never actually happen), but the delivery processes needed to achieve the reduction in acute events.

### Individual patient

The PPB brings the perspective down to that of the individual patient. The patient tends to have two sets in mind when assessing a drug, namely “I’m at high risk” or “I’m at low risk.”<sup>w10</sup> At odds of less than 1 in 100 of personal benefit it becomes clear that the intervention is not particularly effective at the level of the individual patient.

When we are dealing with patients who are at risk, rather than patients diagnosed as having disease, we are effectively asking patients to take a drug for overall public health benefits. These may help them or their neighbour, but no one knows which specific individual it is benefiting because you cannot see a non-event such as a prevented heart attack.

To a general practitioner who is negotiating a treatment plan with a specific patient, the benefits of treatment with a statin are not as compelling as they are at the hospital or public health levels. It may be at this point that many of the apparent “failures of evidence implementation” arise<sup>w7 w8</sup>; general practitioners are often criticised for failing to implement “medical evidence,” when they may be actively making a balanced decision about what matters in a specific instance.<sup>w20 w21</sup> It may also be here that the sharp dichotomy between individually focused consultations and public health imperatives arises.<sup>w16</sup>

### Numbers in a disease scenario

If you consider a disease scenario, the numbers look considerably different from those in a risk reduction scenario (box). An example of this is pneumonia. The absolute risk reduction with antibiotics is large, from about 30% mortality without treatment

# THE EVIDENCE

is vital to apply evidence in medical practice, argue **Peter Davies** and **Seth Jenkinson**



## Disease or risk of disease?

In medicine we deal with two linked but separate concepts. If you have asthma you have a specific disease entity. The disease will need dealing with on its own merits (symptoms, severity); the options of cure, control, rehabilitation, and palliation will be specific to one patient and his or her illness.

If you have hypertension, you do not have a disease. It is an abnormal physiological measurement, in itself not constituting a current disease,<sup>w19</sup> which puts you at higher risk of developing diseases such as heart attack and stroke. The argument for treating hypertension is that it reduces the risk of these long term consequences.

to about 14% in patients who have been admitted to hospital with treatment.<sup>w17</sup> And bear in mind that many more have been treated without hospital admission. The NNT is small and the PPB is high; results are readily seen over a short time scale, and it would be unusual to decline treatment. There is no argument about giving or receiving antibiotics in pneumonia; the debate would be which antibiotic to give.

Conversely, a reason that large trials are needed for certain treatments is that the actual effect in each patient is small. It is only when the results are aggregated across large populations and over time that trends emerge.

### The Rose paradox

This is named after the English epidemiologist Geoffrey Rose.<sup>w18</sup> It explains that a small change made over a large population at risk will make little difference to any one person in that population but will make a huge difference to the overall illness experience of that population. For example, reducing average systolic blood pressure in our country by 5 mm Hg would give a large reduction in the incidence of stroke and myocardial infarction. However, if you were treating a specific patient with hypertension, a 5 mm Hg drop in systolic blood pressure would not be sufficient to reduce his or her risk of cardiovascular events significantly.

Conversely, a big change in the health status of an individual person in a population has little effect on the overall health or illness of the host populations. For example, performing a heart transplant on a patient with cardiomyopathy is of great benefit to that patient, but it has little impact on the overall population health.

The Rose paradox shows that the population perspective and the individual patient perspective are different. The problem is that most of our medical evidence comes from studies of populations rather than narratives of individual cases. However, most day by day medical practice is concerned with the unfolding of medical events in individual patients' cases. And as humans we have a better ear for narrative and people than we do for abstract notions of risk and large numbers of individuals in a population.

Knowing whether you are using a population based or individual based approach is crucial to applying medical evidence accurately. Both viewpoints have merit, but it takes discernment to understand and synthesise the insight of both. The divergence between perspectives of population and individual doctors and patients cannot be bridged by "better implementation of evidence." Fundamental differences between these perspectives are not easy to reconcile.

### Conclusion

Facts are not neutral, and even if they were, humans are not. Every clinical intervention can have its outcome described in terms of the four quantities—RRR, ARR, NNT and PPB. To assess the efficacy of an intervention, we need to know which of these we are using, and the perspective from which we are describing risks and benefits of treatment. It is important to accept that all our presentations of risks and benefits to patients are inherently numerical, even if we soften the numbers to vaguer terms such as "some," "a few," "most," "commonly," or "rarely."

The idea that there is a linear process from data, to presentation to doctors, to presentation to patients, leading to action by patients is

simplicistic. There are changes in perspective on the data at all stages of this chain and what may seem sensible at one level may not be so compelling at another.

Acknowledging the various perspectives on data will lead us away from simple statements such as "this works" and "the evidence shows" towards more specific statements of what works for whom and when. It leads us away from guidelines and back to intelligent negotiation, to distinguish treatment of an established disease from treatment for reducing the risk of a disease, whether as primary or secondary prevention.<sup>w20</sup> The gradual reclassification of risk factors as diseases, "risk factoritis," has led to confusion over applying evidence derived from populations to individual patients who may not need or want our help.<sup>w20</sup>

The parties involved all need to admit that they know part of the truth, but never the whole truth—whether about the evidence, the patient, or the disease.<sup>w21</sup> The next time anyone tells you that "the evidence shows that this treatment works," ask, "From what perspective does this seem to work?" If they do not understand your question, then they do not fully understand the evidence.

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**Competing interests.** PD works as an NHS GP in the United Kingdom and tries to use evidence fairly and accurately in his practice. He participates in the (mostly) evidence based quality and outcomes framework of the current GMS 2 GP contract. SJ has no current financial or other competing interest in the preparation of this article.

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References w1-w21 are on student.bmj.com.