AstraZeneca sued over jab: Could it be down to a misunderstanding of how risk is calculated?

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A multi-million-pound landmark "vaccine damage" case is set to take place in London's High Court. The test case is being pursued by Jamie Scott who suffered a severe brain injury in April 2021 after receiving

the Oxford-AstraZeneca vaccine.

The case being brought under the Consumer Protections Act argues that the Oxford-AstraZeneca vaccine was less safe than consumers were entitled to expect. A key part of the argument is over the efficacy of the vaccine, which claimants argue was "vastly overstated."

AstraZeneca is defending the case.

To get into the nitty-gritty of the claim, we need to understand something about risks. There are two ways to present the change in risk brought about by a treatment or an intervention: absolute risk and relative risk. Let's have a look at an example from my book—The Maths of Life and Death—to explain the difference.

In 2009, under the headline Careless Pork Costs Lives, the *Sun* reported just one of many hundreds of results from a 500-page study by the World Cancer Research Fund on the effect of consuming 50 grams of processed meat per day. The newspaper told readers that eating a bacon sandwich every day would increase their risk of colorectal cancer by 20%.

The *Sun* chose to focus on the "relative risk"—the risk of a particular outcome (developing cancer) for people exposed to a given risk factor (eating bacon sandwiches) as a proportion of the risk for those not exposed. If this relative risk ratio is above one, then an exposed person is more likely to develop the disease compared with someone without the exposure. If it is below one then the risk is decreased.

On the right-hand side of the image below (figure 1), the increase in the relative risk (relative risk ratio of 6/5 or, equivalently, 1.2) of 20% paints a dramatic picture by neglecting the people who are not affected by the disease

The absolute risk can sometimes be a more helpful measure. Absolute risk is the proportion of people exposed or unexposed to a particular treatment or risk factor (for example, eating or not eating bacon sandwiches) who are expected to develop a given outcome (for example, cancer). Eating 50g of processed meat per day increases the absolute lifetime risk of developing colorectal cancer from 5% to 6%.

On the left of figure 1, we consider the fates of two groups of 100 people. Of 100 people who eat a bacon sandwich every day, only one more of them will develop colorectal cancer than in a group of 100 people who abstain.

So it is true that the relative risk for those eating 50g of processed meat per day increases by 20%, but the absolute risk increases by only 1%.

The claimants in the court case argue that AstraZeneca point to studies showing around 70% efficacy at preventing symptomatic COVID. In the court documents, the legal claim states: "In fact, the absolute risk reduction concerning COVID-19 prevention was only 1.2 percent."

The basis of the case that the effectiveness of the vaccine was overstated seems to be, like the *Sun*'s "save our bacon" campaign, that AstraZeneca has inflated the apparent effectiveness of their vaccine by using a relative measure rather than an absolute measure.

Good reasons for using relative risk

There are good reasons why AstraZeneca would have used the relative risk reduction rather than the absolute for describing vaccine efficacy. For one, the prevalence of COVID varied significantly throughout the acute phase of the pandemic. When cases were low, the absolute reduction in risk would necessarily be lower than when the prevalence was high.

Imagine a hypothetical vaccine that blocked half of all infections in two prevalence scenarios: one at 10% and another at 1% prevalence. In the first scenario, the absolute risk reduction from taking the vaccine would be 5%, but in the second it would be 0.5%, whereas the relative risk reduction would always be 50%. In the face of changing prevalence, it makes sense to use the unchanging relative risk reduction to demonstrate how much safer the vaccine makes you.

Another good reason for using relative risk hinges on understanding how clinical trials are often run. Typically, trial volunteers are split into a treatment group that is given the vaccine and a control group that is not.

When running a trial, partly for time constraints and partly because it is unethical to let lots of unvaccinated people get infected, a limit is set on the proportion of people in the unvaccinated group who are allowed to be infected. Once this limit is reached, the trial is halted and the comparison between the proportion of infections in the two groups determines the vaccine efficacy.

Imagine, in a hypothetical trial, this limit was set at 2% and that when the trial was halted only 0.2% of the treatment group had been infected. This would give a crude estimate of the relative efficacy of the vaccine of 90%, but an absolute efficacy of only 1.8%. Even with a vaccine which blocked all infections, it would never be possible to demonstrate an absolute efficacy greater than 2% because of the trial setup.

Given that the UK's Office for National Statistics suggests that we have had enough COVID infections in the UK for everyone to have been infected at least once, using the relative effectiveness seems sensible. Is it reasonable to suggest that statements of the effectiveness of vaccines should be limited because of the trial design or fluctuating prevalence?

Regardless of what the court rules, however, what is not in doubt is that

the Oxford-AstraZeneca vaccine saved millions of lives.

A spokesperson for AstraZeneca said: "Patient safety is our highest priority and regulatory authorities have clear and stringent standards to ensure the safe use of all medicines, including vaccines. Our sympathy goes out to anyone who has lost loved ones or reported health problems."

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