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The terminology we use about medical drugs can be misleading

"Efficacy and safety" and "benefits and risks" of drugs are misleading terms, argues Peter C. Gøtzsche

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We regularly hear that medical drugs, and other treatments or interventions are "effective and safe." This terminology is not only used by the drug industry and drug regulators. Academics also routinely use it in academic papers or research. In clinical practice, we may be told that certain treatments are effective and safe. A recent PubMed search retrieved 80 004 records for "safe and effective" and 29 401 for "effective and safe."

When certain words are used frequently or without deeper scrutiny, they can come to be accepted without question. But when it comes to drugs, the terminology is misleading. No drug is completely safe or without side effects. Drugs always have an effect, otherwise they wouldn't work, so there is always a risk of harm to some people, even if minimal. To call a drug "safe and effective" implies that it can only be good for us.

The arthritis drug Vioxx (rofecoxib) provides an example about the importance of terminology in marketing a drug and how it can be used to avoid liability. Merck withdrew Vioxx from the market in 2004 because it increases the risk of heart attacks and strokes. But in a lawsuit in 2005, Merck was cleared of personal injury because the jury found that Merck had given doctors adequate warning about possible health risks of the drug and did not commit consumer fraud in marketing the drug.[1] Merck repeatedly reminded jurors that the U.S. Food and Drug Administration had approved it as safe and effective on four occasions for use against different types of pain, the last a month before Merck recalled it.[2]

Another misleading terminology that is commonly used about drugs is the benefits and risks of drugs. It implies that drugs always have benefits, but not necessarily harms, only risks of harms. However, in reality, it is the other way around. All drugs have harms, even if small or infrequent, and sometimes they also have benefits.

I joined the CONSORT group for good reporting of trials when it started and co-founded the Cochrane Collaboration the same year, in 1993. In these organisations, I advocated for a change in terminology to stop using the terms "safe and effective" and "benefits and risks." We agreed that we would talk about the benefits and harms of interventions instead. We made this clear when we published CONSORT for harms in 2004.[3]

However, misleading terminology continues to be widely used, often without question. A third misleading concept, also commonly used, is the benefit-risk ratio. The concept is only meaningful if benefits and harms are measured on the same scale, which is rarely the case. It is better to discuss the balance between benefits and harms even though it is subjective as to what people think about this according to the values they attach to various outcomes and how common they are. Given the same data, people might disagree about whether they think the benefits of a treatment outweighs the harms.

There can be a degree of self-interest or conflicts of interest when people make these decisions on behalf of others. When unexpected serious harms emerge after a drug has come on the market, drug regulators will usually tell us that that the benefit-risk balance continues to be favourable or that the benefits exceed the risks.

It is prudent to be sceptical of such reassurances. Drug regulators are very reluctant to admit their mistakes and take dangerous drugs off the market.[4 5] Deaths associated with drug use reported to the U.S. Food and Drug Administration trebled in just eight years, between 2006 and 2014.[6]

Words matter. They influence people's decisions about drugs, other treatments and other interventions. We should therefore abandon misleading terminology and speak about benefits and harms instead.

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1 Mayor S. Merck cleared in personal injury case against Vioxx BMJ 2005; 331:1101 doi: 10.1136/bmj.331.7525.1101-a
2 Major victory for Merck in N.J. Vioxx trial https://www.nbc-news.com/health/health-news/major-victory-merck-n-j-vioxx-trial-flna1c9437294
3 Ioannidis JPA, Evans SJW, Gøtzsche PC, etalCONSORT Group. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004;141:-8. doi: 10.7326/0003-4819-141-10-200411160-00009 pmid: 15545678
4 Gøtzsche PC. *Deadly medicines and organised crime: How big pharma has corrupted health care*. Radcliffe Publishing, 2013.
5 Gøtzsche PC. *Deadly psychiatry and organised denial*. People's Press, 2015.
6 FAERS Reporting by Patient Outcomes by Year. US Food and Drug Administration (as of 15 Nov 2015). Available from: https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/faers-reporting-patient-outcomes-year