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The gap between benefits and harms

Every drug has benefits and harms. In weighing harms against benefits, where does the balance lie?

Drug regulatory agencies evaluate a drug's harm-benefit balance at the general level, using experimental data from clinical trials conducted in a defined population of patients and for a specific indication, in order to decide whether or not to authorise the drug. Healthcare professionals in everyday practice evaluate the harm-benefit balance at the individual level, before prescribing, dispensing or administering the drug to a patient.

At both of these levels, the benefits are gratifying and positive, and offer hope of relief or even cure. Hope is the operative word, however, because the efficacy observed in clinical trials is rarely experienced by every patient enrolled. And trial participants are a selected population who can have different characteristics from patients encountered in everyday practice.

The harms associated with drugs are disheartening for all concerned. They impose limitations and are damaging in various ways. For patients, they mean suffering, disappointment and anxiety. For healthcare professionals, they mean failure and powerlessness. For drug regulatory agencies, they call into question the validity of their decisions. For pharmaceutical companies, they limit profits.

There is a tendency to focus on the hope of benefit, and to put the harms out of one's mind.

But what about our guiding principle: first, do no harm?

If a drug could be guaranteed to have no adverse effects – known, undisclosed or undiscovered – we would try it if there was the slightest hope of efficacy. In reality, all drugs have adverse effects to a varying extent. This is an inherent part of every drug's effects. And the risk of adverse effects means that we need to analyse whether the expected benefit is worth the risk. When deciding whether or not to use a drug, the known adverse effects must be reviewed, factoring in the probable unknowns, and these harms must be weighed against the expected benefits.

By viewing the benefits through the prism of the harms, we avoid just following the latest trend. By rereading the list of very real adverse effects, we avoid using a drug without considering whether this treatment is appropriate.

The gap that makes benefits more attention-grabbing than harms is dangerous. Closing that gap helps us make informed and reasoned decisions.

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