Too much information

Fiona Godlee editor in chief, The BMJ

It’s hard to escape discussing the benefits and harms of drug treatments in a clinical medical journal, and this week is no exception. Under discussion are how best to communicate possible adverse drug reactions, what is the most cost effective steroid for people with adrenal insufficiency, and whether tranexamic acid should be used routinely to reduce bleeding in elective surgery as well as after trauma.

Kirin Tan and colleagues’ Analysis article comes alongside the ongoing debate about the true rate of adverse effects of statins (doi:10.1136/bmj.g5019). The authors ask how helpful is the information provided to patients about possible adverse drug reactions. After reviewing information from 136 drug information documents relating to 15 commonly prescribed drugs, they conclude that it is excessive, inconsistent, often poorly presented, and overwhelmed by symptoms commonly experienced in daily life.

Using data from a recent population based survey published in BMJ Open (doi:10.1136/bmjopen-2014-005374), they list 20 symptoms most commonly reported in the previous seven days, such as back pain, fatigue, and headache. Nine of these are listed in more than half of the drug information documents they reviewed, and eight are listed as an adverse reaction to more than 90% of the drugs they looked at.

What should patients make of this? The authors fear that so many possible harms will deter patients from starting or continuing treatments, or might raise negative expectations and increase rates of reporting of adverse events (the nocebo effect). At the very least, they say, organisations providing information should document the levels of evidence that link the adverse effect with the drug, and where possible provide numerical estimates of risk. They also say that greater reliance should be placed on randomised rather than observational data, except where adverse events are serious or rare. This apparently uncontroversial suggestion will, I have no doubt, raise hackles among those who question the ability of randomised trials to properly report adverse events.

More controversially still, they suggest that clinicians should “contextualise” the information they provide to patients, toning down discussion of common non-specific symptoms to reduce the nocebo effect. They acknowledge that this might be considered patronising but consider this worth the risk for better adherence to effective treatments.

What I don’t see in the paper is any discussion of the role of patient preferences. But this absence reflects much of medicine. And things would be easier if we had better evidence, so that rather than hide information that we believe is unreliable, we could confidently share all the information we have. Certainly the evidence on which a new steroid formulation has been licensed does nothing to inspire confidence. As Anjali Amin and colleagues explain (doi:10.1136/bmj.g4843), a modified release hydrocortisone was approved on the basis of a single non-blinded crossover trial in 64 patients, in which the comparative doses were not equivalent. The authors recommend sticking to the old faithful thrice daily hydrocortisone, or better and cheaper still, once daily prednisolone.

As for tranexamic acid, things are looking good. Jashvant Poeran and colleagues’ retrospective study found that it reduced bleeding after elective orthopaedic surgery without increasing rates of thromboembolism and while reducing rates of perioperative myocardial infarction (doi:10.1136/bmj.g4829). Our editorialists are optimistic (doi:10.1136/bmj.g4934) but they suggest we wait for a properly powered randomised controlled trial before breaking out the champagne.

Cite this as: BMJ 2014;349:g5153

© BMJ Publishing Group Ltd 2014