

EDITOR'S CHOICE

Outcomes that matter to patients

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There's no shortage of examples of clinicians and patients being misled by surrogate outcomes. In some cases the results have been catastrophic. Last year Ray Moynihan reminded us that back in the 1980s flecainide, prized for its effect on reducing arrhythmias, killed tens of thousands of patients (*BMJ* 2011;342:d5160). Citing the 2010 report from the US Institute of Medicine, which urged much greater caution in how we use surrogates, Moynihan called for a shift "from numbers to people" so that patients and doctors stop mistaking "a numerical benefit for a genuine one."

Now John Yudkin, Kasia Lipska, and Victor Montori join the fray (doi:10.1136/bmj.d7995). From their perspective within the world of diabetes they warn that surrogates like HbA_{1c} generally show much larger responses to treatment than "hard" outcomes that matter to patients, such as renal and visual impairment or quality of life. Surrogate outcomes also respond sooner, which makes them popular with drug companies and others doing clinical trials. What the authors call an "alliance of public health advocates, scientists and clinicians, professional societies, and test and treatment companies" then oversees the incorporation of these surrogates into guidelines, quality measures, and pay for performance targets. This is usually done with the best of intentions but with the result that many widely accepted treatment strategies are based on artificially inflated expectations.

The authors call for an end to "the idolatry of the surrogate," in drug regulation and in the way we measure quality and reimburse doctors. The US Food and Drug Administration is taking steps to do this. After the withdrawal of rosiglitazone

(*BMJ* 2010;341:c4848) new hypoglycaemic agents must be evaluated against hard outcomes during rather than after drug development.

Not least among the problems the authors highlight is that surrogate outcomes carry no useful information for patients. "In order to fully engage our patients in treatment decisions, we must understand how therapies affect outcomes that are important to them," they say. This is also the message of the second of our regular columns on communicating risk to patients (doi:10.1136/bmj.e245). Gerd Gigerenzer and Mirta Galesic show how easy it is to confuse patients when we talk in terms of "single event probabilities" with no reference point; for example, saying that they have a 30-50% chance of something happening. Far better, say Gigerenzer and Galesic, to use statements of frequency, such as "if 10 patients take this treatment, three to five of them will experience x."

Focusing on outcomes that matter to patients should improve decision making and patient engagement. It should also stop us spending money on treatments that deliver minimal or no benefit. Michael Cross reports on the use of anonymised outcomes data in commissioning (doi:10.1136/bmj.e66) and John Appleby explains how the NHS in England is using patients' assessments of their health status in ways that could allow us to debate the value of different interventions in different parts of the country (doi:10.1136/bmj.d8191). Both authors warn of substantial challenges ahead.

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