

Sticking to principles and anticipating outcomes

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Summary. The publication of *Unanticipated outcomes*, the personal story of Jerome P. Kassirer, former editor-in-chief of the *New England Journal of Medicine*, gives the opportunity to consider the ethical principles of biomedical and scientific publishing. Conflict of interests, reporting, and fraud affect the credibility of medical communication, which rests on the robustness and transparency of its processes. Not all is yet lost, but we must be guided by strong moral principles and to a consistent framework of values.

About a decade ago two of us decided to estimate the value added by the logo of the *New England Journal of Medicine* (*NEJM*) to a 10-page reprinted report of a randomised controlled trial (RCT). We followed a simple procedure. One of us wrote to the *NEJM* circulation department requesting an itemised estimate for 5000 reprints of the latest RCT. This had to be published in the *NEJM* and have a paper length of 10 pages. Next, we asked our local printer for an estimate to print 5000 copies of the same length and material quality as the *NEJM* reprints, with covers and text of the same length and complexity provided by us. We deducted postage and packing expenses when we compared the two estimates we had obtained.

The result was that the *NEJM* reprints were twenty times more expensive. As the printed content was the same, the difference to the buyer could only be due to administration costs that our local printer did not incur and the quality certification offered by the *NEJM* "brand". The scientific quality seal could not be offered by the printer, but that offered by the *NEJM* would have included selection of probably the most attractive RCTs on offer at the time, the value added by the editorial process and the dissemination of the work by countless outlets worldwide. Even allowing for the value added by a "good" RCT, as certified implicitly by publication on the *NEJM*, the *NEJM* logo added a ten to fifteen-fold value to the product.

As quality is in the eye of the beholder, a big reprint order with a cost way outside the means of any researcher I know, gives a very rough estimate of the value of the *NEJM* logo to anyone wanting such a lot of paper. And they must want it badly to pay such inflated premiums.

Unanticipated outcomes is the personal story of Jerome (Jerry) Kassirer¹, a nephrologist and academic who for eight crucial years was top dog at the *NEJM*. Kassirer described himself as the guardian of a na-

Riassunto La pubblicazione di *Unanticipated outcomes*, la storia personale di Jerome P. Kassirer, ex direttore del *New England Journal of Medicine*, offre l'opportunità di considerare i principi etici dell'editoria biomedica e scientifica. Il conflitto di interessi, le dichiarazioni e la frode influenzano la credibilità della comunicazione medica, che poggia sulla robustezza e sulla trasparenza dei suoi processi. Non tutto è ancora perduto, ma dobbiamo essere guidati da forti principi morali e da un quadro coerente di valori.

tional treasure and fought an apparently ultimately unsuccessful battle with the journal owners (the Massachusetts Medical Society or MMS) to preserve the ethics and independence of his ward. Kassirer was appointed in the summer of 1991 and was fired 8 years later. By this time he had successfully scuppered plans by the MMS to debase the name of the *NEJM* by launching specialist journals (like *NEJM Oncology*) with papers rejected by the *NEJM*, turn the *NEJM* into a publishing group (which eventually came about), move his editorial offices into the "corporate offices" of the MMS and antagonise a number of very powerful bodies such as the American Medical and the National Rifles Associations.

It is interesting and a mark of Kassirer's mental focus on his job that at the time he did not realise that some of the AMA officials were also MMS officers.

Most of all, Kassirer managed to keep clear the distinction between medical ethics and business ethics, making it quite clear that his *NEJM* was written for physicians (a claim modestly confined to New England and possibly American physicians) and was not a marketplace. The terms of Kassirer's firing are vile, for example the MMS insisted on Kassirer not using the term "firing" and tried to stop even Kassirer's family speaking to the media.

As you would expect from a former *NEJM* editor in chief, the book is well written and highly readable, but is also deeply depressing as it charts Kassirer's increasing disagreements with the MMS, as the ending that researchers of my generation well know looms in sight. It is also the story of a human being that implicitly regards his tenure at the *NEJM* as the pinnacle of his professional life. My depression lifted at the very end of my read, when Kassirer clearly explains why the current publishing ethics are failing.

In the last few years we have seen a steady accumulation of evidence from a variety of sources, rang-

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ing from litigation to public campaigns, to freedom of information requests, that the reports of clinical trials published in journals' condensed and compressed form are likely to be (in the rosier cases) datasets which could be subject to explanations alternative to those drawn by the authors. That is, if the data reported in the journals were in sufficient detail to allow alternative explanations to be drawn. Often they are not and my rosy scenario does not take into account the evidence of selection and distortion of methods and results of experiments on humans and our increasingly feeble efforts to purify medicine from fraud²⁻²⁵.

In a situation where publication in famous journals is worth so much extra and our methods for detecting fraud, distortions, poor quality and unnecessary (in one word unethical) research are failing, the value of a journal rests on its credibility. This in turn rests on the ethics and reputation of its editors and the robustness and transparency of its processes. The current editor of the *NEJM* has acquiesced or instigated a lurch towards industry, the only body that can afford the eye-watering reprint charges (and profit from them). The *NEJM* is estimated to have made around \$ 700,000²⁶ from the reprint business from the VIGOR study of Vioxx, a careful piece of marketing which has still not been retracted.

By this stage my few readers will have recognised all the practices obstructed by Kassirer as currently commonplace in one or the other of the big biomedical journals. Which brings me to the conclusion: by making a stand and paying for his principles with his job, Kassirer is showing us that not all is yet lost. We still have a little time before medicine, publishing, science and those who work in them are swallowed up by the marketplace and we must all do what he has done. Stick to principles.

If we do not, the merchants and money changers will have taken over the Temple for good.

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