

EDITOR'S CHOICE

The missing data that cost \$20bn

Kamran Abbasi *international editor*

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Marketing is what you do when your product is no good, said Edward Land, scientist and inventor of the Polaroid instant camera. The same notion filled Tom Jefferson's head when he began to reappraise his initial conclusions about neuraminidase inhibitors and the risk of influenza complications and hospital admissions (doi:10.1136/bmj.g2227). Keiji Hayashi, a Japanese researcher, alerted him to the existence of unpublished trials, trials that were not included in his Cochrane review of 2006. From trusting the literature, researchers, and companies, Jefferson moved to a position of deep scepticism. Many trials were unpublished, data weren't shared, and decisions on purchasing, stockpiling, and using the drugs were based on a slim and skewed representation of the total evidence base.

This week is the culmination of a five year campaign led by Jefferson's Cochrane research team, supported by *The BMJ*, to ensure the release of the full clinical trial data on neuraminidase inhibitors (doi:10.1136/bmj.g2630). The studies, analyses, and editorials in this issue strike like a hammer blow. Oseltamivir (Tamiflu) has generated sales in excess of \$18bn (£11bn; €13bn) for Roche since 1999, something more than the "nice little earner" that a City of London financial analyst described it as (doi:10.1136/bmj.g2524). The United States stockpiled 65 million treatments for a cost of \$1.3bn. The United Kingdom spent £424m on a stockpile of 40 million doses. By 2009, 96 countries possessed enough oseltamivir for 350 million people. GlaxoSmithKline's drug zanamivir (Relenza) was less successful but still generated sales in the region of \$2bn.

The revised Cochrane reviews, which were based on the full clinical trial data, conclude that the benefits of the drugs don't outweigh the harms (doi:10.1136/bmj.g2547; doi:10.1136/bmj.g2545). An analysis of the observational studies finds that they are inconclusive (doi:10.1136/bmj.g2371). So, over \$20bn of public money has been spent on stockpiling drugs of uncertain benefit, and decisions were based on incomplete data.

It isn't hard to see who benefits here, and it clearly isn't patients. Informed choice requires comprehensive and credible information, writes Harlan Krumholz (doi:10.1136/bmj.g2548). Patients, he argues, might choose differently if data owners

released all the relevant information and independent scientists were able to properly analyse and communicate the results. Worryingly, the welfare of patients seems a secondary consideration for all stakeholders. Drug company executives champion their work for the benefit of patients. Regulatory authorities are responsible for protecting patients. Politicians make decisions for the public good. Yet, when faced with the sudden threat of pandemic H1N1 flu, a threat that ultimately did not materialise, each party behaved opportunistically and irresponsibly. Drug companies exploited a window for rapid sales. Regulators approved drugs with insufficient scrutiny, exposed now by the forensic approach of the Cochrane researchers. And politicians were desperate to act, to do something in the face of a perceived crisis, whether it was based on evidence or not. Patient welfare didn't matter, although it was the excuse for these decisions.

The crux of the saga remains the ability of independent analysts to quickly access the full clinical data on any product or device. Initiatives supported by regulators and the industry are being introduced to try to prevent future scandals, but data on existing drugs remain hidden (doi:10.1136/bmj.g2579, doi:10.1136/bmj.g2632). "Everything for me is marketing and publicity, unless proven otherwise," says Jefferson. Companies, regulators, politicians, and researchers might consider the lessons of Tamiflu and put patients first and marketing a nice little earner a distant second.

The full story of *The BMJ's* campaign on Tamiflu is at bmj.com/tamiflu.

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