Sustainable access to innovative therapies: The need to take action on clinical trials transparency

Submission to the OECD Sustainable access to innovative therapies online consultation by the AllTrials campaign and TranspariMED

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The results of clinical trials are used by regulators to decide whether to allow a drug to be sold, and by governments and insurers to decide whether to pay for the drug, and by researchers deciding whether to follow a promising pathway of research on that drug.

Publication bias in clinical trials has been the subject of discussion and research since at least the 1980s. Researchers have consistently found that the evidence base regarding the benefits and harms of medicines is systematically distorted, and routinely overstates the effectiveness of new drugs while understating their harms (side effects). The results of around half of clinical trials are never reported. This is problematic not only regarding clinical trials on new drugs being conducted now, but also for clinical trials that were conducted in the past. Those older trials tested drugs that are essential for current medical practice and contain vital information on the efficacy and safety of today’s medicines; they also set the standards against which tomorrow’s medicines (and their potential benefits against existing cheaper drugs) will be assessed. Those unreported results are at risk of turning into lost results as researchers and software retire.

When the results from trials are kept hidden, decision makers do not have the full information they need to make good decisions. Specifically, due to the unreliable evidence base, regulators, governments and insurers cannot reliably ascertain the benefits of new drugs compared to older generic alternatives. In fact, the evidence base is so fragmentary and unreliable that even within single OECD countries, different government agencies have at times reached different conclusions about the benefits of the same drug.

This directly increases the burden on health budgets because new drugs are far more expensive than generic drugs. Across the OECD and beyond, public and private funds are currently being spent on

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expensive new drugs that may not be more effective or safe than existing treatment options.\textsuperscript{4,5} The sums involved are enormous, as is the potential for savings. For example, over $18 billion was spent worldwide on the drug Tamiflu (oseltamivir) before previously hidden evidence cast doubts on its effectiveness. In 2009, 0.5% of Britain’s entire National Health Service budget was spent on the drug.\textsuperscript{6}

Regulators are aware of the problem, and many regulatory agencies have already taken positive steps on their own initiative. However, implementing comprehensive solutions on the national or global level will require decisive action by political decision-makers.

In line with recent United Nations recommendations\textsuperscript{7}, OECD governments need to assume responsibility for ensuring that all clinical trials are registered and their results fully and accurately reported, and implement measures accordingly. Scalable models for ensuring that all clinical trials are registered and their results fully and accurately reported already exist, as documented in the AllTrials Roadmap.\textsuperscript{8}

Public budgets, taxpayers and patients will greatly benefit from such measures, whose costs are negligible compared to the financial benefits. The only alternative is not to take action, and to continue paying for expensive drugs without reliable evidence on their effectiveness and cost-effectiveness.

**About AllTrials**

The AllTrials campaign for clinical trial transparency was launched in 2013 by Sense about Science, Ben Goldacre, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative and PLOS. It is run by Sense about Science, by Sense about Science USA in the USA and by groups of voluntary campaigners in Ibero-America, Norway and Italy. AllTrials calls for all clinical trials, past and present, to be registered and their methods and results reported. AllTrials is supported by over 700 organisations worldwide. Supporters include the world’s largest medical associations, research organisations, research funders, and medical and scientific publishers; global medical assessment groups; the pharmaceutical company GlaxoSmithKline; universities; and hundreds of patient organisations who between them represent the voices of over half a billion patients.

http://www.alltrials.net/

**About TranspariMED**

TranspariMED seeks to develop actionable policy options for improving clinical trials transparency.

https://www.transparimed.org/


\textsuperscript{7} AllTrials. 2016. “UN calls for global action on clinical trial transparency” http://www.alltrials.net/news/un-calls-for-global-action-on-clinical-trial-transparency/