Are clinical trial data shared sufficiently today?

9 July 2013

Ben Goldacre, research fellow at the London School of Hygiene and Tropical Medicine, says we need all the evidence to make informed decisions about medicines.

The lack of progress on transparency has been startling, he writes. Current estimates suggest that around half of all trials for the treatments being used today have gone unpublished; and that trials with positive results are twice as likely to be published.

There is legislation mandating greater transparency – such as the law requiring trial results to be posted on the website clinicaltrials.gov – but the published evidence now shows that this legislation has been largely ignored.

He also calls for trials from the past to be fully disclosed, since more than 80% of the medicines prescribed this year came onto the market more than a decade ago.

Claims that it's enough for regulators to see all the information on trials expose patients to "real and unnecessary risks," he adds, because problems with evidence are also identified by academics and doctors working outside of regulatory bodies.

He says that Clinical Study Reports – long documents held by regulators and companies on the full methods and results of trials – should be shared publicly, with information about individual patients redacted where necessary. He explains that 1.6 million pages of this material have already been shared by the European Medicines Agency (EMA).

GlaxoSmithKline – the world's fourth largest drug company – has also committed to share all Clinical Study Reports going back to the foundation of the company, as part of the AllTrials campaign.

On the issue of patient privacy, he does not call for individual patient records from trials to be published openly, but does point to several examples of "sensible and cautious sharing of [these] detailed datasets" among professionals.

The problem of missing trials "is one of the greatest ethical and practical problems facing medicine today," writes Goldacre. "The AllTrials movement is driving the solution forwards: patients need industry to engage constructively with this widespread consensus, on the practical details – urgently – so that we can all move on."

But John Castellani, President of the Pharmaceutical Research and Manufacturers of America (PhRMA), says mandatory disclosure could affect patient privacy, stifle discovery, and allow competitors or unscrupulous actors to use the information.

"The biopharmaceutical industry is firmly committed to enhancing public health through responsible reporting and publication of clinical research and safety information," he writes.

He points out that information on clinical trials for potential new medicines is already required by US law to be posted on ClinicalTrials.gov - and says the industry is also "engaged in a dynamic ongoing process to improve on all aspects of clinical trials."

However, he warns that threats to patient privacy "will jeopardize patient willingness to participate in clinical trials, which would delay the availability of new therapies."

Mandatory public disclosure of clinical trial information, without appropriate scientific and clinical context, could also undermine patient trust and confidence in the safety and effectiveness of approved medicines, he writes.

He also raises concerns over disclosure of

intellectual property, confidential commercial information, and proprietary scientific methods found in clinical trials, saying this "could stifle discovery and open the possibility of competitors or unscrupulous actors using the information for their own products in other markets or countries."

He outlines the huge investment and "considerable risk" involved in the search for new treatments, and concludes that "only a carefully balanced regulatory and competitive environment can foster the future investments in this research necessary to produce new treatments to benefit current and future patients."

More information:
www.bmj.com/cgi/doi/10.1136/bmj.f1880
www.bmj.com/cgi/doi/10.1136/bmj.f1881

Provided by British Medical Journal