Call for full access to Tamiflu trial data to allow for independent scrutiny

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Leading researchers today call for access to all clinical trial data (published and unpublished) to allow drugs to be independently assessed by the scientific community.

Tom Jefferson and colleagues from the Cochrane Group argue that the current system for assessing the safety and effectiveness of drugs, based on published trial data only, is "wholly inadequate" and "ethically dubious."

They propose a new approach that would allow in-depth scrutiny of the complete set of trial data for a new drug.

Their call comes after they reviewed the evidence for the antiviral drug oseltamivir (Tamiflu), and were unable to find sufficient published data to support the conclusion that oseltamivir reduces complications in healthy adults.

As a result, Roche (oseltamivir's manufacturer) publicly pledged to make full results for ten unpublished clinical trials available for scrutiny. Yet, to date, they have failed to fulfil this promise.

The Cochrane team's concern deepened after finding reports of ten serious adverse events in patients enrolled in two key manufacturer-funded trials that were not reported in journal publications arising from those trials.

Other recent cases, where the "true" effects of drugs have emerged only after all the evidence (including unpublished data) has been analysed, have further highlighted the importance of independent evaluation.

"The answer is to make the data freely available: we should accept nothing less than a full dataset," say the authors. "Before licensing a drug - and certainly before large purchase decisions are made - our governments and policy makers should ensure that all researchers can access data in sufficient detail to allow for the independent exploration and re-analysis of trials," they add.

Their proposed new approach involves compiling a complete list of drug trials (published and unpublished) and requesting full clinical study reports. It is available at http://www.editorial-unit.cochrane.org/neuraminidase-inhibitors-influenza-hta-project

They urge researchers, the public, and the media to work together to put pressure on industry to embrace the ethical responsibility to release data in the public interest. They also call on medical journals to require submission of the most detailed report available.

They conclude: "It is time the media, the Cochrane Collaboration, and any reader interested in knowing what they are prescribing or are being prescribed increase the pressure on policy makers. If you swallow a medication, you need to know how it works - for real."

Provided by British Medical Journal

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