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Cochrane signs up to AllTrials initiative to campaign for registration and reporting of all clinical trials

London, UK – April 19, 2013 – The Cochrane Collaboration, the international not-for-profit organization that produces systematic reviews of healthcare evidence and the largest database of randomized controlled trials, published online in *The Cochrane Library*, has today formalized its commitment to the AllTrials: All Trials Registered | All Results Reported initiative to campaign for the registration and reporting of all clinical trials.

The AllTrials campaign aims to draw attention to the crisis of unreported trial data. Hundreds of thousands of clinical trials have been conducted from which no or limited data have been made available; data critical to enabling doctors and regulators to make informed decisions about which treatments to use and fund. This is a serious problem for evidence-based healthcare researchers including The Cochrane Collaboration, because all the evidence about a treatment is needed to understand its risks and benefits. Without a complete picture of trial results available, information is lost; bad treatment decisions may be made; financial investment into ineffective treatments are approved by governments and regulators; opportunities for better and more effective treatment are missed; and trials are repeated unnecessarily, duplicating effort and wasting resources.

AllTrials was launched in January 2013 by Ben Goldacre, bestselling author, broadcaster and medical doctor, whose exposé on scientific inaccuracy *Bad Science* (2008) reached #1[1] in the UK paperback non-fiction charts; along with the charity Sense About Science; the Centre for Evidence Based Medicine in Oxford; the James Lind Initiative; and the *BMJ*.

In the three months since its inception, AllTrials has gathered more than 47,000 signatures for its petition calling on governments, regulators and research bodies to implement trial registration and reporting measures; as well as the support of hundreds of organizations and institutions working in

research, patient advocacy and health care. The Cochrane Collaboration was one of the earliest organizations to offer support, and to further demonstrate its commitment to the goals of the AllTrials initiative, has today formalized its involvement as one of the initiative's principal supporters and organizers.

Mark Wilson, Chief Executive Officer of The Cochrane Collaboration: "Patients around the world are being harmed because clinical decisions on their health care are skewed by the absence of clinical trials data. For 20 years The Cochrane Collaboration has been working to give clinicians, researchers and patients the best possible evidence-based information to help them make informed decisions, and it is a scandal that we still do not have access to all trials data so that we can be confident in our conclusions. Already many of Cochrane's thousands of contributors and supporters worldwide have signed the AllTrials petition; I am therefore delighted to formalize the organization's support for the AllTrials initiative."

Tracey Brown, Managing Director of Sense About Science: "We are also delighted to have The Cochrane Collaboration helping to steer the AllTrials campaign. They know very well the struggles that researchers go through to get the clinical trial results they need to produce reliable high-quality reviews. Cochrane has networks of researchers and policy-makers in 120 countries. Their influence and experience is particularly important now that the AllTrials campaign has started to take off internationally."

Dr Ben Goldacre, author of *Bad Pharma*: "It's great that The Cochrane Collaboration has become one of the principal supporters of the AllTrials campaign. We need all the information about the effects of medicines, to make informed decisions about which is best. We've known about the problem of publication bias for three decades, and failed to fix it. We are working with Cochrane to act globally, to protect patients' best interests and to make medicine genuinely evidence-based."

For more information and resources, and to sign the petition, please visit the AllTrials website. To make a financial contribution to support the campaign, please visit the AllTrials fundraising page.

[1]http://www.badscience.net/about-dr-ben-goldacre/

About The Cochrane Collaboration

The Cochrane Collaboration, which this year is celebrating its 20th anniversary, is a global network of scientists, researchers, health policy-makers and consumer advocates that produces systematic reviews of healthcare evidence and the largest database of randomized controlled trials in the world.

More than 28,000 people in 120 countries contribute their time and expertise to a rigorous process of gathering, assessing, and synthesizing research to produce and update Cochrane Reviews. The results are then shared with practitioners, policy-makers and patients to help them make informed and effective choices. Cochrane Reviews are widely considered the highest standard in evidence-based health care. They are published online in *The Cochrane Library*, in English, with a growing selection available in other languages. As a non-governmental and not-for-profit organization, The Cochrane Collaboration operates to minimize bias and remain free from commercial influences, and offers training and guidance to its growing network of contributors.

The Cochrane Collaboration's website can be accessed at http://www.cochrane.org/.

About the AllTrials campaign

The AllTrials campaign for all clinical trials to be registered and the results reported all over the world launched at www.AllTrials.net in January 2013. It is an initiative of Sense About Science, Bad Science, *BMJ*, James Lind Alliance, and Centre for Evidence Based Medicine and now The Cochrane Collaboration. It has the support of 47,000 people and over 250 organizations including more than 100 patient groups. GSK became the first pharmaceutical company to sign up in February 2013.

About clinical trial registration and reporting

Doctors and regulators need the results of clinical trials to make informed decisions about treatments. But companies and researchers can withhold the results of clinical trials even when asked for them. The best available evidence shows that about half of all clinical trials have never been published, and trials with negative results about a treatment are much more likely to be brushed under the carpet [1].

This is a serious problem for evidence based medicine because we need all the evidence about a treatment to understand its risks and benefits. If you tossed a coin 50 times, but only shared the outcome when it came up heads and you didn't tell people how many times you had tossed it, you could make it look as if your coin always came up heads. This is very similar to the absurd situation that we permit in medicine, a situation that distorts the evidence and exposes patients to unnecessary risk that the wrong treatment may be prescribed.

It also affects some very expensive drugs. Governments around the world have spent billions on a drug called Tamiflu: the UK alone spent £500 million on this one drug in 2009, which is 5% of the total £10bn NHS drugs budget. But Roche, the drug's manufacturer, published fewer than half of the clinical trials conducted on it, and continues to withhold important information about these trials from doctors and researchers. So we don't know if Tamiflu is any better than paracetamol.

Initiatives have been introduced to try to fix this problem, but they have all failed. Since 2008 in the US the FDA has required results of all trials to be posted within a year of completion of the trial. However an audit published in 2012 has shown that 80% of trials failed to comply with this law [2]. Despite this fact, no fines have ever been issued for non-compliance. In any case, since most currently used drugs came on the market before 2008, the trial results that are most important for current medical practice would not have been released even if the FDA's law was fully enforced.

We believe that this situation cannot go on. The AllTrials initiative is campaigning for the publication of the results (that is, full clinical study reports) from all clinical trials – past, present and future – on all treatments currently being used. We are calling on governments, regulators and research bodies to implement measure to achieve this. And we are calling for all universities, ethics committees and medical bodies to enact a change of culture, recognize that underreporting of trials is misconduct and police their own members to ensure compliance.

References

1. F Song, S Parekh, L Hooper, YK Loke, J Ryder, AJ Sutton, C Hing, CS Kwok, C Pang, I Harvey. Dissemination and publication of research findings: an updated review of related biases. Health Technology Assessment 2010; Vol. 14: No. 8 http://www.hta.ac.uk/fullmono/mon1408.pdf

2. Prayle AP, Hurley MN, Smyth AR. Compliance with mandatory reporting of clinical trial results on ClinicalTrials.gov: cross sectional study. BMJ. 2012;344:d7373. http://www.bmj.com/content/344/bmj.d7373

The +AllTrials campaign's website can be accessed at: http://www.alltrials.net/

Related resources

Ben Goldacre's Bad Science blog
Joint letter to Members of the European Parliament, 9 April 2013
Tamiflu and trial data (Cochrane.org)
Drug data shouldn't be secret by Peter Doshi and Tom Jefferson, *The New York Times*, 10 April 2012
BMJ open data campaign