Experts propose restoring invisible and abandoned trials 'to correct the scientific record'

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Experts are today calling for all unpublished and misreported trials to be published or formally corrected within the next year to ensure doctors and patients rely on complete and accurate information to make decisions about treatments.

Sponsors and researchers will be given one year to act before independent scientists begin publishing the results themselves using previously confidential trial documents.

The *BMJ* and *PLOS Medicine* have already endorsed the proposal and committed to publishing restorative clinical trial submissions - and will discuss it in more detail at a meeting in London on Friday 14 June 2013.

Unpublished and misreported studies make it difficult to determine the true value of a treatment. Around half of all clinical trials for the medicines we use today have never been published - and a whole range of widely used drugs have been represented as safer and more effective than they are, putting patients at risk and wasting public money.

The authors of the declaration, led by Peter Doshi, a postdoctoral fellow at Johns Hopkins University School of Medicine, will contact manufacturers of trials, asking them to signal their intent within 30 days to publish previously unpublished trials and formally correct previously misreported trials (i.e. to restore abandoned trials).

They propose that if anyone who declares an intention to publish or correct does not do so within one year, all publicly available data for such trials should be considered "public access data" that others are allowed to publish.

This declaration, they say, "offers sponsors and trialists an opportunity to publish or formally correct their studies" – or otherwise see those abandoned studies published or republished by others.

New freedom of information policies means the public and the authors have access to around 178,000 pages of previously confidential trial documents and clinical study reports for widely used drugs for depression, heart disease, epilepsy and influenza. Some trials remain unpublished years after completion, while others have been published but have been shown to contain inaccuracies.

They say they are committed to seeing the findings from abandoned trials published - and misreported trials corrected and republished – and they set out a method for responsibly restoring invisible and abandoned trials (RIAT). "We see RIAT as a collaborative, global effort, and over the next year we hope to discuss and debate our proposal at appropriate venues," they write.

As such, they call on others to join them as volunteers "in place of those who should have but did not make trial reports visible and accessible." And they ask medical journal editors to endorse the concept of restorative authorship to "help the effort to complete and correct the scientific record."

In an accompanying editorial, editors at The *BMJ* and *PLOS Medicine* say Doshi and colleagues "offer a bold remedy" to help restore the integrity of the clinical trial evidence base.

They explain that the results of clinical trials "are a public, not a private, good" and that the public interest "requires that we have a complete view of previously conducted trials and a mechanism to correct the record for inaccurately or unreported trials."

They conclude: "If we do not act on this opportunity to refurbish and restore abandoned trials, the medical research community will be failing its moral pact with research participants, patients, and the public. It is time to move from whether to how, and from words to action."

More information: www.bmj.com/cgi/doi/10.1136/bmj.f2865
www.bmj.com/cgi/doi/10.1136/bmj.f3601

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