

Missing trial data threatens the integrity of medicine

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Missing clinical trial data can harm patients and lead to futile costs to health systems, warn experts in the *British Medical Journal* today as part of an in-depth BMJ review of the matter.

Missing data is a serious problem in clinical research. It distorts the scientific record, so that [clinical decisions](#) cannot be based on the best evidence.

Today the *BMJ* publishes several papers that examine the extent, causes, and consequences of unpublished evidence. They confirm that a large proportion of evidence from human trials is unreported, and much of what is reported is done so inadequately.

In an editorial, Dr Richard Lehman from the University of Oxford and *BMJ* [Clinical Epidemiology](#) Editor, Dr Elizabeth Loder, describe a "culture of haphazard publication and incomplete data disclosure." They call for more robust regulation and full access to raw trial data to allow better understanding of the benefits and harms of many kinds of treatment.

A study by Beth Hart and colleagues finds that including unpublished data in published meta-analyses of drug trials often changed their results. They argue that access to full trial data is needed to allow drugs to be independently assessed.

Two further studies show poor adherence to requirements for mandatory

trial registration and timely sharing of results. Ross and colleagues show that fewer than half of US National Institutes of Health funded trials are published in a peer reviewed journal within 30 months of completion, while Andrew Prayle and colleagues find that only 22% of trials subject to mandatory reporting had results available within one year of completion.

"When the word 'mandatory' turns out to mandate so little, the need for stronger mechanisms of enforcement becomes very clear," write Lehman and Loder.

Other studies published today highlight the many difficulties researchers face when they try to assess the true harms and benefits of common interventions.

Lehman and Loder believe that concealment of data is "a serious ethical breach" and that clinical researchers who fail to disclose data "should be subject to disciplinary action by professional organisations."

They conclude: "These changes have long been called for, and delay has already caused harm. The evidence we publish shows that the current situation is a disservice to research participants, patients, health systems, and the whole endeavour of clinical medicine."

Provided by British Medical Journal

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