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Calls for greater transparency in the release of clinical trial data

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Researchers have called for greater transparency in the public release of clinical trial data after a study revealed significant under-reporting of side effects in medical treatments.

The study, led by the University of York, revealed that the medical benefits are routinely reported, while the side effects are incompletely documented in peer-reviewed journal articles.

The clinical benefits of new drugs are usually tested in randomized clinical trials, in which patients are randomly assigned to receive drug or placebo, before drugs can be prescribed widely.

Adverse events, or side effects, are also routinely collected in such trials, and should be reported in scientific journal articles to give a clear picture of the benefit and risks of new treatments.

The study, published in *PLOS Medicine* found that 64% of side effects would have been missed by readers looking only at published reports about the medical treatments studied.

The authors conclude that full reporting of adverse events is essential to allow patients and doctors to assess the balance between benefits and side effects of medical treatments.

Dr Su Golder, Research Fellow at the University of York's Department of Health Sciences, said: "We need more transparency.

"People need to have access to full information about the harm from medical treatments, so that they are aware of the consequences of choosing a particular treatment."

In one example, 198 deaths were recorded in clinical trials of four new drugs, and full details on the cause of death for all the participants were available from the pharmaceutical company dataset. In the subsequent published papers only 29 deaths were fully reported.

In another example, an unpublished report documented 15 suicides in drug treated participants, but only seven were revealed in published papers.

Dr Golder added: "There are serious concerns that the published findings represent only a small snapshot of the full dataset, and that patients and healthcare professionals may be making decisions based on incomplete information."

The study, which included collaboration with Gill Norman, University of Manchester and Yoon Loke, University of East Anglia, was funded through the National Institute for Health Research (NIHR).

Provided by University of York