

EDITORIALS

The new *BMJ* policy on sharing data from drug and device trials

Is a necessary first step towards the full sharing of all anonymised trial data

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BMJ

Last month the *BMJ* announced a new policy on sharing data from clinical trials.¹ From January 2013, trials of drugs and medical devices will be considered for publication only if the authors commit to making the relevant anonymised patient level data available on reasonable request.² This new policy will apply to any paper that reports the main endpoints of a randomised controlled trial of one or more drugs or medical devices in current use, whether or not the trial was funded by industry (box).

Why the new policy? Because it is no longer possible to pretend that a report of a clinical trial in a medical journal is enough to allow full independent scrutiny of the results. Journals are, of course, not the only potential channel for such scrutiny, but as long as publication remains the main currency for academic recognition, journals have a responsibility to use what power they have to push for greater transparency. If research is to help doctors and patients make the best clinical decisions, it must be reliable and reproducible, but these are qualities that current peer review processes cannot assure.

Since announcing the new policy we have been asked why it applies only to trials of drugs and devices, what is meant by “relevant,” and who will judge whether a request is “reasonable.” We have started with drugs and devices as being the area of medicine where most evidence exists for incomplete and misleading trial publication, but we expect that the policy will extend to cover all clinical trials. “Relevant data” encompasses all anonymised data on individual patients on which the analysis, results, and conclusions reported in the paper are based. As for “reasonable request,” the *BMJ* is not in a position to adjudicate, but we will expect requesters to submit a protocol for their re-analysis to the authors and to commit to making their results public. And we are at least able to make the transaction transparent. We will encourage those requesting data to send a rapid response to bmj.com describing what they are looking for. If the request is refused we will ask the authors of the paper to explain why.

Does the new policy represent a big change? The extensive media coverage would suggest so. But we see it as just one step up from our current policy: since 2009 we have encouraged

authors to share their data on request and have required them to say whether they will or not. The results across the *BMJ* and *BMJ Open* have been promising: many of our authors now say that they will share their data on request, and one *BMJ*² and 23 *BMJ Open* papers have datasets posted on Dryad, the digital repository with which we have partnered (<http://datadryad.org>). A survey of triallists published in the *BMJ* this week gives further cause for optimism. Joe Ross and colleagues emailed 683 corresponding authors of trials published in the six major general medical journals. About three quarters of the 317 who responded said that they thought data sharing through data repositories should be required, and a similar proportion said that data sharing should be required in response to individual requests.³

But the policy has clear limitations and is by no means the end of the story. The *BMJ* publishes relatively few trials of drugs and devices. Of the 226 research papers published so far this year, 31 were the main reports of randomised controlled trials, of which most were trials of health services. Six trials were of drugs, none were of devices, and only one of the drug trials was sponsored by industry.⁴ The *BMJ*'s new policy is a signal, but it won't change things on its own. The *Annals of Internal Medicine* and *PLoS Medicine* both have policies on data sharing.^{5,6} We hope that other journals will follow, and we look to the International Committee of Medical Journal Editors, of which the *BMJ* is a member, to take a decisive lead.

But because many trials never get published in journals at all,⁷ real change will come only when the regulators raise their game. Here too there is scope for optimism. After pressure from the Nordic Cochrane Centre,⁸ the European ombudsman ruled that the European Medicines Agency had been wrong to hold clinical trial data as commercial in confidence. The agency's new director general responded by announcing earlier this year that the agency would publish clinical trial data once a drug has been approved.⁹ A workshop this week aims to hammer out the details.¹⁰

If patient anonymity is assured, the most efficient and effective option must be open deposition of patient level data with the underlying code and background documentation. However,

many practical problems are still to be resolved. All the signs are that the initial approach will fall short of this ideal, with a focus instead on availability on request. Contracts will therefore need to be agreed between data “owners” and “requesters.” This is not straightforward, as illustrated by negotiations with GlaxoSmithKline over data on its neuraminidase inhibitor zanamivir (Relenza) (bmj.com/tamiflu) and by the Yale University open data access project and its critics.^{11 12} The European Medicines Agency will also fall short of expectations if it does not extend retrospectively its commitment to encompass data on older drugs still in current use. The oseltamivir (Tamiflu) saga suggests that opening up historical datasets will be as important to patient care and healthcare budgets as anything done prospectively.¹³

But these new policies are a step in the right direction. Our first substantial target is to achieve proper independent scrutiny of trials of all drugs and devices in current use. Journals and their contributors will now have to ensure that we are as rigorous in overseeing and critiquing this new breed of re-analyses as we have tried to be of the originals.

Competing interests: None declared.

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To which papers does the *BMJ* policy apply?

We hope that authors will be inclusive rather than parsimonious when committing to make data available. And we will keep an open mind about the types of clinical trial that are eligible. At a minimum, however, the *BMJ* policy applies to papers reporting studies with these characteristics:

- **Clinical trial**—The International Committee of Medical Journal Editors, of which the *BMJ* is a member, defines a clinical trial as “a research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome”
- **Main endpoints**—Pre-specified primary outcome(s) and harms
- **Drug**—This means a medicinal product for human use. The UK Medicines and Healthcare Products Regulatory Agency defines a medicine as “any substance or combination of substances presented as having properties for treating or preventing disease in human beings; and any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis”¹⁴
- **Medical device**—There are many kinds of medical device for use in healthcare. Our policy is aimed most squarely at what the US Food and Drug Administration calls class III devices, “those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.”¹⁵ Examples include pacemakers, stents, and prostheses.

The *BMJ* policy does not currently apply to trials of diagnostic tools or surgical operations or of any other interventions that are not drugs or devices.

The policy applies to papers submitted from January 2013, regardless of when the trials were conducted and regardless of the sources of funding and sponsorship for the trial.