Medical Xpress

Nearly 90 percent of clinical trialists think data should be more easily shared

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Nearly nine out of ten clinicians carrying out biomedical research trials believe that trial data should be shared more easily, even though they do express some practical concerns, a study published today on *BMJ* website reveals.

BMJ has long championed transparency in medical research. Last month, the journal launched an open data campaign to compel greater accountability in healthcare, and from January 2013, it will require a commitment from trialists to make their data available on reasonable request.

Dr Fiona Godlee and Dr Trish Groves (*BMJ* Editor and Deputy Editor) say that this decision has been made because "it is no longer possible to pretend that a report of a clinical trial is sufficient to allow full independent scrutiny of the results". They say that this new policy is a "step in the right direction" and it is now down to journals and their contributors to "ensure that we are as rigorous in overseeing and critiquing this new breed of reanalyses as we have tried to be of the originals".

Major regulators are also beginning to contemplate far-reaching open data access policies, most notably the European Medicines Agency.

Many trialists have advocated for data sharing to enhance the value of trial data. It has been argued that full access to data reduces the potential for incomplete reporting of study outcomes therefore improving medical evidence and clinical decision making.

Data sharing generally takes place either via depositing in a repository or after a request from an individual. However, despite compelling evidence, studies have shown that researchers of clinical studies are among the least likely to share their raw data due to concerns over research subject confidentiality and diminished rewards for conducting original research.

Researchers from Yale University, BioMed Central and the Dana-Farber Cancer Institute therefore carried out a survey on authors of trials published in 2010 and 2011 in the six journals with the highest Impact Factor 2011 – *New England Journal of Medicine, The Lancet, JAMA, Annals of Internal Medicine, PloS Medicine* and the *BMJ*. All responses were anonymous. Respondents were asked about concerns regarding: sharing data through repositories, receiving and making data sharing requests, reasons for declining or granting requests and their beliefs on the right of first use of trial data.

315 trialists completed the survey, the majority of which were male, between 50 and 64 years of age and who had completed their training between 10 and 24 years ago. 83% were employed by an academic institution and two thirds had reached the rank of full professor.

88% of respondents supported data sharing with 75% believing that sharing data through a repository should be a requirement. 73% thought investors should be required to share data upon individual request while only 18% of trialists were required by the research funder to deposit their trial data.

Only five (2%) respondents indicated that data should be made available to investigators immediately upon trial completion; 109 (35%) thought between one to two years after completion; 97 (31%) within three years and 104 (33%) said there should be no time limit and right of first use should extend until the main findings are accepted for publication.

Concerns with data were varied including: appropriate data use (65%), investigator and funder interests (41%) and protection of research subjects (29%). Other, more specific concerns were patient confidentiality and consent, while recognition was the reasoning behind denying individual requests for 42% of respondents. The most common reason for denying individual requests was ensuring appropriate data use at 74%.

And while some trialists themselves may have shown reluctance to share data, fewer than a fifth were required by their funders to deposit trial data in a repository and fewer than half had received an individual request. The researchers say this, however, may be a consequence of an under-developed data sharing system.

The researchers suggest that due to this, the concerns that trialists have need to be addressed. They suggest that to ensure competency, training curriculums can be developed to teach the best practices for preparing and using shared clinical trial data. They say there is also a need to ensure trialists receive sufficient recognition but addressing these concerns will require a "cultural shift" with academic institutions and promotions needing to begin crediting investigators.

In conclusion, the researchers found "substantial support" for sharing clinical trial data among researchers of recently published trials in high impact general medical journals. They say that "practical concerns must be addressed" and the community "needs to not only cooperate with these efforts, but trust that data sharing is in best interests of public and science".

More information: Sharing of clinical trial data among trialists: a cross sectional survey, *BMJ*.

Provided by British Medical Journal

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