The Academy of Medical Sciences

January 2013

President's statement

Views from Academy President, Professor Sir John Tooke PMedSci on the debate surrounding the publication of clinical trial data.[1]

We welcome a debate on improving the availability of data from clinical trials and look forward to considering this issue in detail in our response to the House of Commons Science and Technology Select Committee's inquiry into clinical trials and disclosure of data. Our response will reinforce our support for mechanisms to make clinical trial data available to inform research for the benefit of patients, subject to appropriate safeguards of confidentiality of participants and of course assuming that the research is scientifically sound.

There is a particularly strong case for making the findings of research that involves patients available. If society contributes to the generation of evidence, then it is only fair that it is accessible to all.

The need for publication of trial data

Negative results can be helpful in identifying alternative uses for drugs or highlighting patterns in responders and non-responders that might indicate sub-populations where the drug might be more effective. We therefore support efforts to address the difficulty in publishing negative data from clinical trials. I have had direct experience of being unable to persuade a journal to publish a negative proof of concept study exploring the potential of a new class of drug. Considerable investment in this field continued for a number of years before finally being abandoned.

What and when to publish

There are a number of issues around the publication of clinical trial data that need to be considered before deciding what does and does not constitute research misconduct. These include the development of mechanisms to enable the release of data in a form that is both accessible and useful and avoids being misleading. It is not as simple as just publishing raw data – it must be analysed in informed and validated ways to avoid spurious conclusions being drawn that can cause unnecessary concerns about particular drugs or screening programmes. Impartial scientists could have a role to play in ensuring that meta-analysis and data synthesis (i.e. drawing together the results of multiple trials) are subject to the same rigour as that afforded to primary research. Finally failure to ensure the confidentiality of those involved in clinical trials is itself an issue of research misconduct.

[1] Information in this document was sent to Research Fortnight in December 2012. The document has also been shared with Academy Fellows submitting views to the Academy's response to the House of Commons Science and Technology Select Committee's inquiry into clinical trials and disclosure of data

In terms of research conduct, the Academy is a supporter of the Universities UK research integrity concordat which commits to ensuring rigour, transparency and open communication when reporting research data, including the sharing of negative results.

Due to the complexity of the issues involved it is unlikely that a 'one size fits all' approach (i.e. every trial being published within a year of completion) will be appropriate.

Ethics committees

We have welcomed and indeed initiated the establishment of the Health Research Authority that has oversight of the entire health research process. We are pleased that they will now follow up the commitments that researchers made to publish the outcomes of their research when they originally applied for ethics approval. We hope that they will also consider the extent to which failure to publish should be considered in future assessments.

A need for legislation

The issue is a European, if not global one and has to be approached on an international level. Therefore, it is not clear that there is a need for changing UK legislation on this issue at the present time. However, we welcome the announcement of the House of Commons Science and Technology Committee's inquiry into this issue, we will be submitting evidence, and hope that this will inform ongoing discussion about whether legislation is appropriate.

The role of professional bodies

We think that many professional bodies have been and continue to consider this issue, but as highlighted earlier this topic is complex and must be considered properly. The Academy has been working for some time on the broad spectrum of issues associated with the regulation and governance of health research and the use of patient data in research. This issue does not just affect the UK – pharmaceutical companies are often global – and the transparency of clinical trials data has been raised in discussions with our sister academies around the world. We look forward to continuing our conversations with them on this topic. As previously highlighted, the Academy and many other professional bodies are supporters of the Universities UK research integrity concordat which commits to ensuring rigour, transparency and open communication when reporting research data, including the sharing of negative results.