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Protocols, probity, and publication

The role of ethics in research extends through the moral obligation to report that research and to do so in an honest, transparent, and timely manner. Authors have as great a duty of care to readers, research colleagues, and society as they do to their study participants and sponsors. To help authors demonstrate that their findings are faithful to their research protocol, *The Lancet*, *The Lancet Oncology*, and *The Lancet Neurology* offer to publish links to the full study protocol on the authors' institutional website. Authors are invited to take advantage of this voluntary service, which is inaugurated by a publication in this month's edition of *The Lancet Oncology*.¹ Protocol links will be offered for any design of study and will be encouraged for randomised controlled trials (RCTs), because these are the bedrock on which secure clinical decisions are made.

Full and unbiased reporting of prespecified analyses is essential for the credibility of research and the care of patients. Reporting of RCTs has improved with the introduction and adoption of CONSORT guidelines,² the International Committee of Medical Journal Editors' encouragement that protocols be submitted to journals in parallel with manuscripts,³ and the prospective registration of trials.⁴ But experience at *The Lancet* and elsewhere⁵ suggests that, despite these measures and increased editorial oversight, reporting often does not mirror the protocol on which funding, ethical approval, and participants' consent will have been based. Research on protocols submitted to the US Food and Drug Administration for licensing showed that, in several instances, studies whose data did not show benefit had been published subsequently as showing benefit.⁶ At *The Lancet*, where a protocol review service has been available since 1997 to help authors improve the quality of trial design,⁷ and where, since 2002, randomised trials have been reviewed with

the accompanying protocol,⁸ discrepancies in endpoints and analysis still occur.⁹

Selective reporting undermines both the values and value of research. By enabling readers to readily visit a study's protocol, we hope to increase the accuracy of trial reporting and to make internal and external validity clearer. As a result, we believe that research can be more rapidly translated into practice. Accessible protocols will also help future researchers to design better studies and will help to generate more accurate systematic reviews. Access to documents after conclusion of a trial is not a novel idea,^{10,11} but in an age of increasing expectations and transparency, we believe that it is an idea that should now be put into practice.

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