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LETTERS

DATA SHARING ON REQUEST FOR TRIALS

Open access to economic outcome data will help to bridge the gap between clinical trials and clinical guidelines

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Buoyed by a burgeoning medical culture of "appropriate use" and rising doctor awareness of the financial ruin that threatens many patients who navigate expensive treatments in pursuit of better health, medical specialist societies have grown increasingly vocal about integrating economic value in their clinical guidelines.[1] These encouraging developments are, however, threatened by a worsening decline in the generalisability of randomised controlled trials, a concern supported by widening differences between the characteristics of patients enrolled in trials and those of the populations targeted for intervention outside trials.[2-4]

Randomised clinical trials are the highest level of evidence for comparative health effectiveness, but they also provide the highest evidentiary standard for comparative cost and cost effectiveness. Although many cost effectiveness analyses are performed with sophisticated mathematical models, we believe that economic evaluations performed alongside randomised trials with individual participant data will have an increasingly important role (figure⇓). However, because patients in randomised trials often differ substantially from patients in the target population the generalisability of within trial cost effectiveness can be significantly threatened by the heterogeneity of treatment effects.[3] By interacting with differences in generalisability and thereby distorting cost effectiveness, treatment heterogeneity is a challenge to the integration of economic analyses in specialist society guidelines and health policy.

We propose that trialists enrolling populations that differ substantially from target populations should share individual participant economic data so that researchers can determine how these differences affect cost effectiveness.[5] The use of economic outcomes in guideline development by specialist societies is a reasonable and encouraging step towards providing patients and doctors with transparent information about value. Addressing the pitfalls in the process promises to improve the societies' decision making and patient care. Public dissemination of study data will greatly help.[6]

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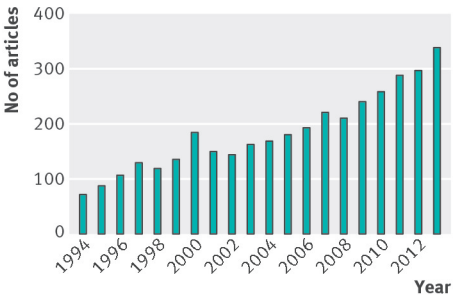
Figure



Numbers of publications of randomised controlled trials in PubMed that include an economic evaluation. Search terms included the medical subject headings cost-benefit analysis and randomised controlled trial