

Clinical trial metadata: defining and extracting metadata on the design, conduct, results and costs of 125 randomised clinical trials funded by the National Institute for Health Research Health Technology Assessment programme

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Scientific summary

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Background

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme, established in 1993, has published the results of over 100 randomised controlled trials (RCTs) with some 220 more in progress. Although trial registries contain some key prospective features of trials, data are absent on the actual conduct, performance and cost of trials.

Objectives

The aim of the project was to develop and pilot questions describing clinical trials funded by the HTA programme in terms of it meeting the needs of the NHS with scientifically robust studies.

The objectives were:

- to develop, pilot and validate metadata definitions and classification systems to answer specified questions within six themes
- to extract data under these headings from published RCTs funded by the HTA programme
- to analyse these data to answer specific questions grouped by theme
- to consider further development and uses of the data set, including refinements of the metadata headings for their application to ongoing and future HTA trials.

A database was developed, 'populated' using retrospective data and assessed for its ability to answer questions under six prespecified themes. The themes were:

1. How was the trial seen as meeting the needs of the NHS?
2. How well designed was the trial?
3. How well conducted was the trial?
4. Were the statistical analyses appropriate?
5. What, if any, kind of economic analysis was performed?
6. What was the cost of the trial?

Methods

Questions were screened for feasibility in terms of data available or readily extractable. Answers were assessed by completeness, success of the classification system used and difficulty of data extraction. Each question was scored to be retained, amended or dropped.

Results

One hundred and twenty-five RCTs were included in the database from 109 monographs. Neither the International Standard Randomised Controlled Trial Number nor the term 'randomised trial' in titles proved a reliable way of identifying RCTs. Only limited data were available on how the trials aimed to meet the needs of the NHS. Most trials were shown to follow their protocols but updates were often necessary as hardly any trials recruited as planned. Details were often lacking on planned statistical analyses but we did not have access to the relevant statistical plans. Almost all the trials reported on cost-effectiveness, often in

terms of both the primary outcome and quality-adjusted life-years. The cost of trials was shown to depend on the number of centres and the duration of the trial. Of the 78 questions explored, 33 were answered fully and 28 would require amendment if the analysis were to be updated. The other 17 questions could not be answered with readily available data.

Conclusions

Metadata on RCTs can be expanded to include aspects of design, performance, results and costs. The HTA programme should continue and expand the work reported here.

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HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: <http://www.nets.nihr.ac.uk/programmes/hta>

This report

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