The opportunities and challenges of pragmatic point-of-care randomised trials using routinely collected electronic records: evaluations of two exemplar trials

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Declared competing interests of authors: Tjeerd-Pieter van Staa was previously employed (now with the University of Manchester), and Gerard McCann, Shivani Padmanabhan and Rabah Belatri are currently employed by the Clinical Practice Research Datalink (CPRD). CPRD operates within the Medicines and Healthcare products Regulatory Agency (MHRA; the UK regulatory authority for medicine, medical devices and trials and a UK Trading Fund organisation). CPRD provides data and trial services on a commercial basis for both academic and pharmaceutical industry researchers. Neither CPRD nor MHRA had any role in writing the report, or had any input into the content of the report. The authors Gerard McCann, Shivani Padmanabhan and Rabah Belatri were not involved in the review and analysis of research governance challenges and obstacles with the trials. Tjeerd-Pieter van Staa reports grants from the Wellcome Trust, during the conduct of the study; grants from National Institute for Health Research (NIHR), grants from pharmaceutical companies, grants from FP7 Innovative Medicines Initiative (IMI), outside the submitted work. Ben Goldacre reports grants from the Wellcome Trust, during the conduct of the study, and receives income from speaking and writing about problems in medicine, including our failure to conduct trials efficiently where there is uncertainty about treatments. Liam Smeeth reports grants from the Wellcome Trust, during the conduct of the study; grants from the Medical Research Council (MRC), grants from NIHR, and personal fees from GlaxoSmithKline (GSK), outside the submitted work. Munir Pirmohamed is a NIHR Senior Investigator, and is a Commissioner on Human Medicines, and chairs its Pharmacovigilance Expert Advisory Group. Martin Gulliford was member of the CPRD Independent Scientific Advisory Committee (ISAC) throughout the period of this report. None of the other authors has any competing interests to declare.
Doctors and the NHS have a duty to ensure that prescribed medicines are both safe and effective. A randomised trial is considered the best method to evaluate the effects of medicines. In a randomised trial one or more groups of patients receive different treatments or sometimes no treatment, in order to compare the results in the different groups. However, trials which compare different medicines that aim to do the same thing (‘head-to-head comparisons’) are not routinely done. Most general practitioners (GPs) use computers to keep their medical records. In this study we wanted to find out if it would be possible and useful for the NHS to use these electronic health records (EHRs) to carry out the research that is usually done in trials. We therefore carried out two small trials and interviewed NHS staff and patients. We found that GPs were required to fill in many forms, which took considerable time and effort, before being allowed to ask patients to take part in the trials. As a result, only about 5 out of 100 GPs completed all of the paperwork. Although most of the GPs expressed strong support for EHR trials, they did not have time for this extra paperwork. One trial recruited all the patients required, while the other trial only recruited one-fifth of its target. The 10 patients who were interviewed all said that being recruited into a trial during a consultation with their GP was acceptable, as was the use of their electronic health record for the trial. Our conclusion is that EHR trials are feasible but the burden of red tape needs to be reduced. The use of electronic records to undertake research could greatly simplify trials of medicines.
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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 07/50/05. The contractual start date was in July 2011. The draft report began editorial review in January 2014 and was accepted for publication in April 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

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