

Use of the electronic health record in the design and conduct of clinical trials (Workshop R40R): October 2013 – October 2014

Co-applicants: Professor Paula Williamson, Professor Carrol Gamble, Professor Mike Clarke, Professor Julia Brown, Dr Dermot O'Reilly, Dr Michael Lay, Professor Liam Smeeth, Dr Athene Lane, Professor James Carpenter, Professor Helen Snooks, Professor Ian Ford and Dr Catrin Tudur-Smith.

Summary/list of the original objectives:

1. A survey of UK CTUs with respect to their use of health informatics in trials.
2. Identify case studies of approaches to using the Electronic Patient Record (EPR).

What was actually achieved?

1. A survey of UK and Ireland CTUs was undertaken to gather information on how they: (i) identify available data sources and assess them for suitability in relation to recruitment feasibility assessment; (ii) identify potential patients for studies via the electronic patient record and the challenges they experience; (iii) use the EPR for outcome data collection and determine the suitability of such data sources.
2. Case studies from the survey were presented at the workshop.

Workshop held: Monday 23rd June 2014, Manchester

Background

This was a joint workshop organised by members of the MRC Hubs for Trials Methodology Research (HTMR), All-Ireland Hub for Trials Methodology Research and the Farr Institute. It was attended by members of the HTMR, representatives of clinical trials units in UK and Ireland, e-Health Informatics Research Centre (e-HIRC), Health e-Research Centre (HeRC) and industrial delegates. It focused on discussing the role of electronic health records (EHR) in supporting clinical trials.

The purpose of the workshop was to create a networking opportunity for delegates with an interest in using electronic databases for: supporting feasibility assessments of trials, identifying and contracting eligible patients and outcome data collection. It was also an opportunity for delegates to share their experiences of their interaction with EHRs.

Summary

55 delegates from the MRC HTMR, Farr Institute, e-HIRC, HeRC and pharmaceutical industry attended the workshop which comprised 4 sessions on the use of electronic databases in supporting trials and a small group session to exchange ideas about methodological research priorities to advance this research area.

Overview of use of routinely collected health data in trials

This session gave an historical perspective of how routine data were collected in the past. It then provided an outline of the current landscape about routine data sources and some examples of long term trials that had generated follow up data were presented. In addition the creation of a UK-wide database which combined primary and secondary care data was mentioned and the presenter indicated that Scotland was close to having such a data resource. The three topic areas to be discussed during the day were introduced.

A survey of UK Registered CTUs

A survey which aimed to identify (i) the types of electronic database resources being used by CTUs to support clinical trials and (ii) their experiences with these resources was presented. The overall response rate was 78% (35/45 CTUs). The survey was classified into 3 topic areas: (1) Assessment of the feasibility of recruitment, (2) Identifying and contacting eligible patients; and (3) Outcome data collection. The advantages and disadvantages of using electronic databases were also presented.

Topic 1: Feasibility assessments using routine electronic data sources

Two examples were presented of how routine data sources were used for feasibility assessment of 2 very different trials.

Topic 2: Identifying and contacting eligible patients

Two examples of how eligible patients were identified and contacted were described.

Topic 3: Outcome data collection using the EHR

Two examples were presented of how EHRs have been used to collect outcome data.

Small group work: Methodological research priorities

Delegates were assigned into five small groups comprising individuals from multiple disciplines (CTU directors, statisticians, information systems/information technology leads, pharmaceutical industry representatives and trial coordinators) in order to discuss three questions. These were:

1. What are the barriers and facilitators to using electronic health records in trials?
2. What do CTUs and trialists need to know in this area?
3. What methodological research or guidance is needed? (and identify the top 3 with highest priority).

Responses have been grouped to inform a research agenda for health informatics.

There was no requirement for an AV technician since the sessions were not recorded.

Expected workshop outputs

The outputs from this proposal will be:

- A report of the one-day workshop which will include a comprehensive summary of the presentations and discussion. We will approach the journal *Trials* to see if they would be interested in publishing this.
- Development and submission of a grant application to the MRC MRP.
- Establishment of a dialogue between the HTMR, e-HIRC and CTU Networks, as well as with the relevant research community in Ireland.

Actual Workshop Outputs

Slides from six of the eight workshop presentations will be made available via links from the workshop summary on the MRC HTMR Network website. Discussion highlighted topics for the health informatics in clinical trials research agenda. The opportunity to publish the feedback from the meeting in a peer-reviewed journal paper was discussed. The specific scope and content of such a paper are currently under consideration.

Next steps

The publication will be written up and submitted to an open access journal.