HTMR project R25 – Jon Deeks Midlands Hub – Final Report

Remits, roles and working models for Trial Steering Committees and Data Monitoring Committees in clinical trials evaluating diagnostic tests, most notably test accuracy studies.

Project end date 31st March 2014

The objectives were stated as:

1) To review existing guidance to identify roles of TSC and DMCs for RCTs of interventions, and to assess how roles translate for clinical trials of diagnostic test accuracy and other trials of test evaluation

2) To review the roles and working models of TSC and DMCs in ongoing and completed trials of diagnostic test accuracy and other trials of test evaluation

3) To develop a consultation document on the possible working models and roles of TSC and DMCs for clinical trials of diagnostic test accuracy and other trials of test evaluation for consultation

4) To host an expert consensus workshop to discuss the consultation document and reach consensus on TSC and DMC remits, roles and working models for use

5) To produce documents for use in funding agencies and by DMCs and TSCs in for clinical trials of diagnostic test accuracy and other trials of test evaluation

6) To create a research agenda of inadequately addressed issues in the functions of TSC and DMCs for clinical trials of diagnostic test accuracy and other trials of test evaluation

Objectives 1 and 2 were completed by undertaking reviews of literature on DMC and TSC remits, surveying funders' policies for independent committees, and the roles and working models used in a sample of test accuracy studies. These findings were presented at the "International Symposium on Methods for Medical Test and Biomarker Evaluation" at the University of Birmingham in July 2013.

We then undertook an analytical mapping exercise to identify linkages between the roles of committees, the working models that they require (in terms of independence and unblinded data review) to deliver on those roles, and then investigated how these roles varied across test evaluation studies of difference designs. From this we developed a proposal document for the expert consensus workshop (objective 3).

The workshop was help in September 2013 in Birmingham (objective 4). At the meeting we reviewed our findings, but then focused in small group work using case studies identified our surveys to prompt in depth discussion and identification of the key issues involved. Professor Peter Croft from the University of Keele acted as an excellent facilitator for these discussions.

Following the meeting we distilled the findings into a set of proposals, based on a risk based model of test evaluation studies. We have undertaken two rounds of iteration with the workshop participants by email, and have now reached consensus agreement on the proposals (attached). We are delighted to have achieved a simple output from the meetings (objective 5).

We are now in the process of writing an accompanying explanatory article to go with the proposal document, and will target a top general medical journal for publication. We identified during the project much ignorance amongst researchers of how test evaluation studies impact on patients' risks and outcomes, and will included illustrations of the different mechanisms in the article. The article will also list areas where further research is required (objective 6).