

Measuring the impact of diagnostic tests on patient management decisions within three clinical trials

Sue Mallett¹, Stuart A. Taylor², Gauraang Batnagar², STREAMLINE COLON Investigators, STREAMLINE LUNG Investigators, METRIC Investigators

¹*Institute of Applied Health Research, University of Birmingham, Birmingham UK B15 2TT*

²*Centre for Medical Imaging, University College London, Charles Bell House, 43-45 Foley Street, W1W 7TS*

Background: Standard studies comparing diagnostic tests measure diagnostic test accuracy. Some trials also provide information on additional outcomes such as time to diagnosis and the number of additional tests in patient pathway. Ideally diagnostic tests would be compared as interventions in randomised controlled trials (RCTs). However RCTs for comparison of diagnostic tests as interventions can be problematic to design and run. Problems include long time periods required for studies following patient outcomes during which either test or treatment pathways change, high numbers of patients required, high costs, ethical issues about randomizing to receive tests, difficulty understanding role of diagnostic test as complex intervention, plus other barriers. We present three examples where we have measured how tests affect patient management decisions within diagnostic accuracy trials.

Aims: To describe methods and insight from three clinical trials recently completed measuring the impact of diagnostic tests on patient management.

Methods: Three trials, each comparing alternative diagnostic tests or diagnostic test pathways against a reference standard of normal clinical practice have been designed to collect patient management decisions. In each patient management decisions based on the alternative pathways are reported based on eight or ten alternative management options. STREAMLINE COLON and LUNG compare whole body MRI to current NICE recommended pathways for detection of metastases at diagnosis of colon and lung cancer respectively. METRIC compares ultrasound and MRI for diagnosing the extent and activity of Crohn's disease in newly diagnosed and relapsed patients.

Results and discussion: Additional analysis, subsequent to prior main trial results, are ongoing to explore impact of patient management decisions by linking detailed analysis of patient diagnosis and management decisions. These three trials provide insight into the design, analysis issues and how measuring patient management decisions in a clinical trial can provide important information on the role and uses of diagnostic tests.

Keywords

Diagnosis, impact, patient management, accuracy, clinical trial