Are studies of diagnostic tests supported?

A diagnostic test is an indicator or predictor of an illness state. As such the term needs to be interpreted broadly as it includes tests used to help make a diagnosis or screen for a disease, tests to stage disease, to monitor treatment, and to estimate prognosis.

There a number of types of diagnostic study which will be considered by National Institute for Health Research (NIHR) Programmes:

a) The first of these is the development of a new test or instrument and/or the broad assessment of its reliability and validity. These might range from questionnaires that identify mental states to molecular assays. Test development and/or testing for psychometric properties or analytic validity, as it is called in the ACCE framework*, are only supported to the extent that the test technology is well-developed and forms part of a clear pathway into further research which directly promotes patient benefit.

b) Diagnostic accuracy studies examine the clinical validity of a test, that is whether the changes in the measure reflect changes in disease state or risk, and usually assess a new test against a gold-standard or reference one. Such studies are likely to report sensitivity and specificity, positive and negative predictive values and receiver operating characteristic (ROC) in a defined population.

c) Diagnostic utility studies examine the value of a diagnostic test in improving patient outcomes, and are often designed as trials and powered on relevant clinical endpoints. Economic outcomes may also be important.

In terms of which NIHR programme to apply to:
  • Application can be made to the Invention for Innovation (i4i) Programme which funds innovative technologies that offer significant patient benefit. Otherwise for test development and assessment of test properties, the Research for Patient Benefit (RfPB) Programme is an appropriate funding source if the trajectory into patient benefit is likely to be short.
  • Stand-alone studies of diagnostic accuracy are most likely to be submitted to RfPB.
  • Studies of diagnostic utility (even if they also contain components looking at diagnostic accuracy) should be submitted to the Health Technology Assessment (HTA) Programme.
  • Diagnostic utility studies should be submitted to Efficacy and Mechanism Evaluation (EME) Programme if they included studies of mechanisms or promote understanding of pathophysiology.

*ACCE stands for:
  • Analytical validity
  • Clinical validity
  • Clinical utility
  • Ethical, legal and social implications of genetic testing