ABSTRACT

The goal of test evaluation is to provide evidence that the new test improves patient outcomes or produces other benefits without adversely affecting patient outcomes. Tests may improve patient outcomes if they improve the selection of treatment by providing more accurate diagnostic, prognostic or predictive information than existing tests; or if they are safer or offer other attributes such as improved patient acceptability.

In principle, randomized controlled trials (RCTs) comparing the new test strategy and subsequent treatment with current best practice will provide the best evidence about the impact of the new test on patient outcomes. However these RCTs are not always available.

This presentation describes an approach for deciding when evidence of test accuracy and safety can be linked to evidence from existing treatment trials to infer patient outcomes and when new RCTs are required. This approach involves specifying the potential benefits of the new test and whether it will be used as an add-on, triage or replacement to existing tests to identify the critical questions for evaluation and sources of comparative evidence.