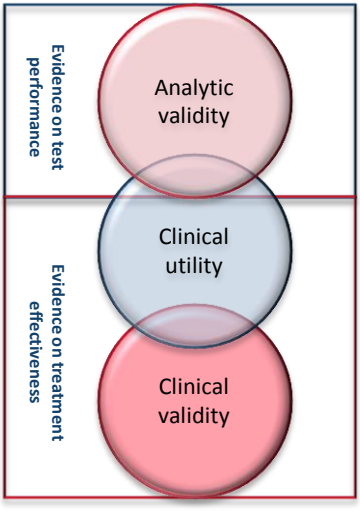
Challenges associated with assessing co-dependent 'test and treat' technologies

Sally Wortley, Toby Gould and Lukas Staub (presenter)
Systematic Reviews and Health Technology Assessment, NHMRC Clinical Trials Centre, The University of Sydney

Medical technologies have traditionally been categorised as either diagnostic tests or interventions. Increasingly assessments of co-dependent technologies are being required, especially in the assessment of targeted therapies. Assessments of such technologies must consider both the evidence on accuracy of the diagnostic test and the effectiveness of treatment predicted by the test. An example is the use of EGFR mutation testing to guide treatment with the tyrosine kinase inhibitor gefitinib in patients with lung cancer.

Co-dependent technologies are those where the use of each technology needs to be combined to achieve or enhance the effect of either technology.



The assessment of EGFR testing and treatment with gefitinib has tended to address issues of **clinical validity** and **clinical utility**.

As the efficacy of treatment with gefitinib is impacted by the performance of EGFR testing, it is important that aspects relating **analytic validity** are also considered.

Three questions central to assessing EGFR mutation testing with gefitinib are:

1. **What is the analytic validity of the test?** How well can testing detect the presence of EGFR mutations?
2. **What is the clinical validity of the test?** How reliably can EGFR testing predict response to treatment with gefitinib?
3. **What is the clinical utility of the test?** What is the likelihood that pre-treatment EGFR mutation test results will influence a decision to treat a patient with gefitinib?

Assessment agencies have varied in their consideration of each of these key questions

Agency	Analytic validity	Clinical validity	Clinical utility
MSAC[1] (Australia)	Partial	✗	✗
PBAC[2] (Australia)	N/A	✓	✗
National Institute for Health Research[3] (UK)	✓	✓	✓
Ontario HTA[4] (Canada)	Partial	✓	✓

Conclusions: An important element in the appraisal of co-dependent technologies is the need to consider the benefits of the joint use of each technology. A challenge in the assessment of co-dependent technologies will be the development of approaches specifically designed to inform the applicability of evidence regarding a given test in tandem with downstream therapeutic performance.

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