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Title **Epidermal Growth Factor Receptor Mutation Analysis in Advanced Non-Small Cell Lung Cancer: A Review of the Clinical Effectiveness and Guidelines**

Agency **CADTH, Canadian Agency for Drugs and Technologies in Health**
Suite 600, 865 Carling Ave, Ottawa, Ontario K1S 5S8 Canada;
Tel: +1 613 226 2553, Fax: +1 613 226 5392; publications@cadth.ca, www.cadth.ca

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Aim

To assess the clinical effectiveness of epidermal growth factor receptor (EGFR) mutation analysis using polymerase chain reaction (PCR) to identify patients with advanced non-small-cell lung cancer (NSCLC) who are likely to respond to treatment with tyrosine kinase inhibitors (TKI); to assess the diagnostic performance of polymerase chain reaction-based methods that are used to evaluate EGFR mutations in patients with advanced NSCLC ; and to assess the quality of guidelines on testing for EGFR mutations in patients with NSCLC.

Conclusions and results

Evidence from observational studies suggests that PCR-based approaches can be used to identify mutations in the EGFR gene with a similar sensitivity to that of direct sequencing. PCR-based tests are likely useful for identifying patients with NSCLC who are likely to respond to treatment with a TKI. In several studies, genetic material was microdissected from tumor-rich areas. This may require additional expertise and incur cost. Most of the studies did not use a commercially available reagent kit. Commercially available kits may have quality-control advantages over assays developed "in-house" as regards quality control in a clinical laboratory setting.

Methods

A literature search encompassed key health technology assessment resources, international health technology agencies, and a focused Internet search. The search was limited to articles published in English. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, controlled clinical trials, observational studies, and guidelines. Two independent reviewers screened articles using predefined criteria. Any disagreements were resolved through discussion until consensus was achieved.

Written by Mujoomdar M, Moulton K, and Spry C, CADTH, Canada