

Carbon-13 Urea Breath Test for *Helicobacter Pylori* Infection in Patients with Uninvestigated Ulcer-Like Dyspepsia: OHTAC Recommendation

Ontario Health Technology Advisory Committee

October 2013

Suggested Citation

This report should be cited as follows:

Ontario Health Technology Advisory Committee (OHTAC). Carbon-13 urea breath test for *Helicobacter pylori* infection in patients with uninvestigated ulcer-like dyspepsia: OHTAC recommendation [Internet]. Toronto: Queen's Printer for Ontario; 2013 October. 10 p. Available from: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/urea-breath-test-ohtac-rec>

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Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

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When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

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This report was prepared by Health Quality Ontario or one of its research partners for the *Ontario Health Technology Advisory Committee* and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to Health Quality Ontario. It is possible that relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations>.

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Background

An evidence-based analysis (<http://www.hqontario.ca/en/documents/eds/2013/full-report-urea-breath-test.pdf>) was conducted by the Medical Advisory Secretariat Collaboration to answer the following research question:

- What is the diagnostic accuracy and clinical utility of the carbon-13 urea breath test (¹³C UBT) for detecting *Helicobacter pylori* in adults with uninvestigated ulcer-like dyspepsia who have no alarm features?

Conclusions

- The ^{13}C UBT is an accurate diagnostic test with high sensitivity and high specificity.
- In head-to-head comparisons with serology, the ^{13}C UBT has comparable sensitivity but higher specificity.
- There is no standardized protocol for performing the noncommercial ^{13}C UBT, and the procedure can vary according to many factors.
- Further, studies that evaluated the performance of the ^{13}C UBT used various composite reference standards.
- There is a paucity of data on the use of the ^{13}C UBT beyond test accuracy.

Decision Determinants

A decision-making framework developed by the Ontario Health Technology Advisory Committee (OHTAC) consists of 7 guiding principles for decision making and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into health system. For more information on the decision-making framework, please refer to the *Decision Determinants Guidance Document* (<http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework>).

The decision determinants for this recommendation are summarized in Appendix 1.

On the basis of the decision determinants, OHTAC favoured continued use of serology as the first-line diagnostic test because of less concern about false-positive results compared with false-negative results. However, for recurrent episodes in which the serology test result is unreliable, coverage has been recommended for the ¹³C UBT.

OHTAC Recommendations

- OHTAC recommends that serology remain the first-line diagnostic test for *H. pylori* in adults with dyspepsia who do not present with alarm features, for whom endoscopy is not indicated.
- OHTAC recommends coverage for the ^{13}C UBT in patients who have been treated successfully for a previous episode of *H. pylori* infection and now have recurrent symptoms that could be due to reinfection.

Appendices

Appendix 1 – Decision Determinants

Decision Criteria	Sub-criteria	Decision Determinant Considerations
Overall Clinical Benefit	Effectiveness	¹³ C UBT appears to be an accurate test for detection of <i>Helicobacter pylori</i> infection in adults with uninvestigated dyspepsia and no alarm features. In head-to-head comparisons with serology, ¹³ C UBT has comparable sensitivity but higher specificity (GRADE: Low)
	Safety	No safety concerns were identified
	Burden of Illness	Dyspepsia is a common condition reported by 29% of Canadians. <i>Helicobacter pylori</i> is one of the causes of dyspepsia. The estimated prevalence of <i>H. pylori</i> infection in Ontario is 23%, with older people and immigrants at higher risk. Approximately one third of patients presenting to primary care with dyspepsia are infected with this bacteria
	Need	<i>Helicobacter pylori</i> is an important cause of chronic gastritis, peptic ulcer disease, mucosa-associated lymphoid tissue lymphoma, and gastric cancer. It is categorized as a class I carcinogen by the World Health Organization
Consistency with Societal/Ethical Values	Societal Values	False-positive results are associated with unnecessary treatment (i.e., personal financial burden), possible side effects, allergies, potential development of <i>Clostridium difficile</i> colitis (low risk but not zero), and fostering drug resistance. False-negative results are associated with persistent symptoms and possible progression to ulcers or gastric cancer. False-negative results are less desirable than false-positive results. One study has shown that most primary care patients who have undergone serologic testing would be willing to undergo the ¹³ C UBT, but only if they are told that the latter is more accurate ^a
	Ethical Values	
Value for Money	Economic Evaluation	The commercial ¹³ C UBT kit is more expensive than serology. The additional cost to the Ontario health system of using the ¹³ C UBT is \$7.8 million
Feasibility of Adoption into Health System	Organizational Feasibility	The current standard test is serology, which is performed by public health laboratories and covered by the Ontario Health Insurance Program. With the ¹³ C UBT, commercial kits are needed to standardize processing. Further, specialized measuring equipment is necessary

Abbreviation: ¹³C UBT, carbon-13 urea breath test.

^aMcNulty C, Whiting JW. Patients' attitudes to *Helicobacter pylori* breath and stool antigen tests compared to blood serology. J Infect. 2007;55(1):19-22.

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