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Horizon scanning prioritising summary

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Breath test for lung cancer detection in high-risk patients

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PRIORITISING SUMMARY

REGISTER ID: 000122

NAME OF TECHNOLOGY: BREATH TEST FOR LUNG CANCER DETECTION

PURPOSE AND TARGET GROUP: LUNG CANCER SCREENING FOR HIGH- RISK PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|------------------------------|---|
| <input type="checkbox"/> Yes | ARTG number |
| <input type="checkbox"/> No | <input type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United Kingdom	✓		
United States	✓		

IMPACT SUMMARY:

Mensanna Research (USA) provides a breath test with the aim of detecting lung cancer. The technology is not currently available in Australia.

BACKGROUND



The lung breath test is a non-invasive test that measures volatile organic compounds (VOCs) in exhaled breath to predict the probability of lung cancer. A portable collection apparatus captures the VOCs in one litre of breath into an absorbent trap. The absorbent trap is then analysed by gas chromatography and mass spectroscopy.

The breath collection apparatus is shown in the adjacent figure (printed with permission: Menssana

Research Inc). The high-risk subject wears a nose clip and breathes in and out through a disposable mouthpiece. The long tube is the breath reservoir, and the small tube affixed to its

end is the absorbent trap. The front panel of the breath collection apparatus shows the flowmeter on the left and a digital timer on the top right (Menssana Research 2004). Previous research has identified breath markers of oxidative stress, the breath methylated alkane contour, which distinguishes breath of patients with and without lung cancer (Phillips et al 1999, Phillips et al 2003, Gordon et al 1985, Menssana Research 2004).

CLINICAL NEED AND BURDEN OF DISEASE

Lung cancer is the most common cause of cancer death in males and the fourth leading cause of cancer in Australia (AIHW 2003). In 2001, 5278 males and 2782 females were newly diagnosed with cancer of the lung, bronchus or trachea (AIHW, 2004). The mortality rate for lung cancer is high with approximately 90% of patients diagnosed with lung cancer succumbing to the disease. Five-year survival rates are poor at approximately 10% (AIHW, 2003).

DIFFUSION

Population lung screening utilising the breath test is not offered in Australia. The manufacturer suggests the breath test may serve as a primary tool in the investigation of high-risk patients, followed by secondary screening with CT and final testing with bronchoscopy.

COMPARATORS

Current methods for diagnosing lung cancer in Australia include chest X-ray, chest CT, bronchoscopy and lung biopsy.

EFFECTIVENESS AND SAFETY ISSUES

The most recent and largest study of the Menssana breath test for lung cancer compared breath samples between 178 bronchoscopy patients and 41 healthy volunteers (Phillips et al, 2003).

Breath samples from the bronchoscopy group were collected prior to procedure and analysed to determine the alveolar gradients of particular VOCs (a cross-sectional study). Of the 178 bronchoscopy patients 91 were disease-free, 15 had metastatic lung cancer, 67 had primary lung cancer and 5 patients had an indeterminate result. The 67 primary lung cancer patients' breath samples were then compared to the 41 healthy volunteers' samples (diagnostic level IV evidence). A predictive model employing nine specific VOCs identified primary lung cancer with a sensitivity of 89.6% (60 of 67 patients) and a specificity of 80.5% (33 of 41 volunteers).

COST IMPACT

The manufacturer is yet to determine the cost of the test (personal communication, Menssana Research).

In 1993–94 the total health care expenditure on lung cancer was estimated at A\$107 million. This estimate includes hospital, medical, pharmaceuticals, nursing home and allied health services, public health programs, research, other institutional and non-institutional and administration expenditure. During the same period total treatment costs per case of lung cancer were estimated at \$14,298 (Mathers et al 2004).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

It is not known whether early detection of lung cancer can improve disease outcome. However, the study authors claim that early detection in the United States could improve the 5-year survival rate from 20% in patients with stage 3 lung cancer (see Appendix), and up to 70% in patients with stage 1 disease (Phillips et al 2003).

CONCLUSION:

There is limited evidence available (diagnostic level IV evidence) for the effectiveness of the Mensanna breath test for the detection of lung cancer. However, the burden of disease in Australia from lung cancer is high and there is potential for its application to complement more invasive methods of diagnosing lung cancer.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

Australian Institute of Health and Welfare (AIHW) & Australasian Association of Cancer Registries (AACR) 2003. *Cancer in Australia 2000*. AIHW cat. no. CAN 18. Canberra: AIHW (Cancer Series no. 23).

Australian Institute of Health and Welfare (2004). *Interactive Cancer Data* [Internet] Available from: <http://www.aihw.gov.au/> [Accessed 7th October, 2004].

Cancer Council Australia (2004). *Clinical Practice Guidelines for the Prevention, Diagnosis and Management of Lung Cancer*. [Internet] Available from: <http://www.nhmrc.gov.au/publications/pdf/cp97.pdf> [Accessed 7th October, 2004].

APPENDIX:

Stages of cancer

The staging of a carcinoma has to do with the size of the tumour, and the degree to which it has penetrated. When the tumour is small and has not penetrated the mucosal layer, it is said to be stage I cancer. Stage II tumours are into the muscle wall, and stage III involves nearby lymph nodes. The rare stage IV cancer has spread (metastasised) to remote organs (Medline Plus 2002).