Title:	Urovysion Fluorescence In Situ Hybridisation (FISH) Assay
Agency:	Medical Services Advisory Committee (MSAC) Mail Drop Point 106 Commonwealth Department of Health and Ageing GPO Box 9849 Canberra ACT 2601 Australia http://www.msac.gov.au
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Aim

To assess the safety, effectiveness and cost-effectiveness of adopting the Urovysion FISH Assay in conjunction with cystoscopy compared to cystoscopy alone to diagnose recurrence of transitional cell carcinoma (TCC).

Conclusions and results

Safety: UroVysion FISH Assay is a safe, non-invasive test performed on voided urine.

Effectiveness: The sensitivity of the UroVysion test ranged from 48% to 86%, and the specificity ranged from 34% to 100%. Based on these results and consideration of various pretest probabilities of recurrence, the clinical impact of adopting Urovysion is likely to be greatest in patients with a high risk of TCC recurrence who have undergone at least 1 year of follow-up. In these patients, using the UroVysion test to select whether a follow-up cystoscopy under local anaesthetic (following a negative Urovysion test) or general anaesthetic (following a positive Urovysion test) is required means that only a small number of patients would unnecessarily undergo cystoscopy under general anaesthetic, and most patients would undergo only one cystoscopy, rather than two. The probability of missing a recurrence following a negative Urovysion increases in patients with higher risks or in patients at later stages in their follow-up.

Cost-effectiveness: An economic model showed that the costs of adopting UroVysion exceed the costs of current practice. At five years, the cost of adopting UroVysion was $7835, compared to $5959 for current practice. One-way sensitivity analyses showed that under any plausible variation of evidence of accuracy, costs or rates of recurrence, the use of the UroVysion test remained more costly than current practice with the equivalent expected clinical outcomes.

Recommendation: MSAC recommended that on the strength of evidence pertaining to Uroysion FISH assay public funding should not be supported for this procedure. The clinical usefulness of the test is limited by the sensitivity and expense of the test and the cost effectiveness was not demonstrated. The Minister for Health and Ageing accepted this recommendation on 28 March 2006.

Method

MSAC conducted a systematic review of the biomedical literature (Medline; EMBASE; Pre-Medline; Current Contents, The Cochrane Library) from 1966 to March 2005. Reference lists and health technology assessment websites were also searched. An economic model was used to compare the cost-effectiveness of adopting the Urovysion test to select whether a patient being monitored for TCC recurrence undergoes cystoscopy under local or general anaesthetic versus standard practice where patients initially undergo cystoscopy under local anaesthetic followed by a second cystoscopy under general anaesthetic if the initial cystoscopy is positive.