The cost-effectiveness of a novel SIAscopic diagnostic aid for the management of pigmented skin lesions in primary care: a decision-analytic model
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The objective was to assess the cost-effectiveness of the MoleMate system for the management of pigmented skin lesions (moles), in patients aged 18 years or older, in primary care. The authors concluded that the system could be cost-effective, compared with best practice, but there was considerable decision uncertainty. The reporting and methods were generally good, and the authors’ conclusions were appropriate.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to assess the cost-effectiveness of the MoleMate system, for the management pigmented skin lesions (moles), in patients aged 18 years or older, in primary care.

Interventions
The intervention was best practice plus the MoleMate system, and the comparator was best practice alone. Best practice was an assessment by a lead clinician, including clinical history, visual examination, and seven-point checklist, as recommended by the National Institute for Health and Care Excellence (NICE). The MoleMate system was a handheld spectrophotometric intracutaneous analysis (SIA) scanner, in primary care, with a diagnostic algorithm, to improve the management of suspicious pigmented skin lesions, and to reduce unnecessary referrals. The lead clinician made the final diagnosis and referral decision.

Location/setting
UK/primary care.

Methods
Analytical approach:
The constructed model was a decision tree, with Markov chains, which combined the data from a UK trial (see Other Publications of Related Interest) with other published data. The lifetime costs and outcomes were estimated for a 45-year-old patient, with one suspicious lesion. The authors stated that the perspective was that of the UK NHS.

Effectiveness data:
The key effectiveness inputs were the sensitivity and specificity of the lead clinician's diagnosis, for each pathway. These were from the randomised controlled trial (MoleMate UK Trial) of 1,293 patients from 15 general practices in the East of England. Sensitivity was the percentage agreement between the clinician's diagnosis and the subsequent expert's decision to biopsy or monitor. Specificity was the percentage agreement between the clinician and the expert that a lesion was benign. Other clinical inputs were from the MoleMate UK Trial, UK life tables, the literature, or expert opinion, if necessary.

Monetary benefit and utility valuations:
Utility values were assigned to each of the cancer states (no cancer, and stages zero to four). The authors assumed that patients with no cancer had perfect health (utility of one). The utilities for stages zero to four were assumed, based on a 2004 study, which elicited utilities from 1,109 patients with melanomas at stages one to three, using the time trade-off approach. This study was identified by a search of the Tufts Cost-Effectiveness Analysis Registry.
Measure of benefit:
The measure of benefit was the quality-adjusted life-year (QALY). Future benefits were discounted at an annual rate of 3.5%.

Cost data:
The direct costs incurred by the NHS were analysed. These included general practitioner (GP) consultations; chemotherapy, radiotherapy, and biopsy; intervention; X-rays, scans and tests; and surgery and follow-up. The cost of the MoleMate system was based on assumptions for its duration of use, maintenance, and the number of patients presenting (48 per 10,000). The cost of the system was from the manufacturer. Most other costs were from NHS Reference Costs for 2008 to 2009. All costs were reported in 2011 UK £. Future costs were discounted at an annual rate of 3.5%.

Analysis of uncertainty:
One-way sensitivity analyses were performed to assess the impact of uncertainty in key parameters on the results. A scenario was analysed, using trial data for the prevalence of melanoma at diagnosis, and East of England cancer registry data for the stage at diagnosis; to be more relevant for the English context. Probabilistic sensitivity analysis was conducted to assess the impact of joint parameter uncertainty on the results. Value of information analysis was conducted to assess the expected value of perfect information and perfect parameter information.

Results
The MoleMate strategy had a sensitivity of 98.4% and specificity of 82.1%; best practice had a sensitivity of 95.6% and a specificity of 89.2%. Over 45 years, the MoleMate strategy had an expected cost of £1,133 and gained 15.108 QALYs. Best practice had an expected cost of £1,115 and gained 15.098 QALYs.

The MoleMate system had an incremental cost-effectiveness ratio (ICER) of £1,896 per QALY gained. The likelihood that the system was cost-effective, at a willingness-to-pay threshold of £30,000 per additional QALY, was 66.1%.

In the scenario with East of England cancer registry data, MoleMate had an ICER of £3,172 per QALY gained, and a 76.5% likelihood of being cost-effective at the £30,000 threshold.

The one-way sensitivity analyses showed that the results were sensitive to varying the sensitivity of each option, and the price of the scan. The maximum expected value of perfect information was £43.1 million, at the £30,000 threshold.

The expected maximum value of perfect parameter information was £32.2 million, for the sensitivity and specificity of the MoleMate system, compared with best practice; £13.5 million for the risk of progression in undiagnosed and untreated disease; and zero for the other parameters.

Authors' conclusions
The authors concluded that the MoleMate system could be cost-effective, compared with best practice, but there was considerable uncertainty.

CRD commentary
Interventions:
The intervention and comparator were clearly described, and best practice was an appropriate comparator. The authors pointed out that best practice might not be the usual care, and conclusions about the cost-effectiveness of the system relative to usual practice should be made with caution. No other comparators were considered.

Effectiveness/benefits:
The effectiveness estimates were clearly reported. Key details of the trial used to derive the estimates were reported. The trial appears to have had good methods and been UK specific. There was no discussion of other trials evaluating the system or similar systems, so it remains unclear if other relevant evidence was missed. There was no discussion of the identification and selection of the sources for the other clinical inputs. The authors justified their decision to use prognosis data from a US study, stating that it was the largest prospective cohort study of melanoma prognosis. The method of selecting the source for the utilities appears to have been reasonable.
Costs:
The costs were clearly reported and appropriate for the adopted perspective. Most of the costs were specific to the UK. Re-inflation of the costs to the price year was not discussed; since some costs were from previous years, they should have been inflated to 2011 prices. This may have been done, but was not explicitly stated, and the inflation rate was not reported.

Analysis and results:
Appropriately, an incremental analysis was conducted. The model was clearly described and a diagram was supplied. A variety of methods were used to investigate and characterise uncertainty; some of these could have been reported in more detail. An expected value of information analysis was presented. The absolute differences in the expected costs and QALYs for the MoleMate system, compared with best practice, were small, and there was considerable decision uncertainty, as indicated in the probabilistic sensitivity analysis and the value of information analysis. This was driven primarily by the sensitivity and specificity of the MoleMate system versus best practice, and the risk of disease progression in undiagnosed melanoma. The authors suggested that research should focus on reducing the uncertainty in these parameters.

Concluding remarks:
The reporting and methods were generally good, and the conclusions were appropriate.

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Other publications of related interest

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