Framingham Risk Score

The Framingham Risk Score is a well-accepted tool to estimate the 10-year risk of developing coronary heart disease (CHD). However, many patients fall into the intermediate risk category. Improved discrimination within the intermediate risk category is necessary to prevent CHD and side-effects of statins therapy efficiently. The Circulating Cells consortium plans to develop a biomarker test to decide whether patients with an intermediate risk should be treated with statins. The aim of our study was to estimate the potential lifetime effectiveness and cost-effectiveness of a novel biomarker test based on currently available information.

Methods: The prognosis of patients with an intermediate risk was simulated with a decision analytic Monte Carlo model to estimate the potential lifetime costs and effects (life-years (LY)) for three strategies: treat all patients with statins, treat none of the patients with statins or use a test to select patients for statin treatment. Costs were calculated for the Netherlands using a healthcare sector perspective. Values for all input parameters were derived from the literature.

Results: A strategy using a perfect test for a 55-year old man would be slightly more expensive than the treat-none option (£1966 vs. £1941) but less expensive than the treat-all option (£5374). The test and the treat-all option would be equally effective (24.45 LY) and more effective than the treat-none option (24.3 LY). The test-based strategy cost £25 more than the treat-none strategy and provides 0.147 more life years. Furthermore, the test option dominates the treat-all option. Given 100% sensitivity and 100% specificity the test shows an ICER of £170 per Life Year gained versus the treat-none option.

Results were sensitive to uncertainties regarding model parameters such as the sensitivity, specificity and costs of the test, as well as CHD risk, and the costs and effectiveness of statins. In figure 2 acceptability curves show the importance of the sensitivity and specificity on the acceptability of the biomarker test. When the performance of the test decreases the ICER increases and therefore the percentage that the test will be accepted decreases. The other options become more favourable.

Main findings:
- Many patients with an intermediate Framingham Risk score will not develop coronary heart disease
- A biomarker test can be used to decide which patients with an intermediate risk should be treated with statins
- A cost-effectiveness analysis can be used to calculate the potential economic and health impact of a biomarker test
- Use of a biomarker test can lead to greater costs than the treat-none option but it can lead to some health gain
- The stratifying biomarker test has the potential to reduce costs and still achieve the same effects as the treat-all option
- The input values used in the model can be adjusted whenever needed

Conclusions: A test to reclassify patients in the Framingham intermediate risk group into higher and lower risk categories has the potential to optimize cost-effectiveness by preventing CHD and reduce the risk of drug side-effects. Values used in this model (e.g., test sensitivity and specificity) can be adjusted whenever needed to determine whether continued development of a biomarker is worthwhile.