An economic evaluation of a laboratory monitoring program for renin-angiotensin system agents

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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
This study examined the cost-effectiveness of extended laboratory monitoring during renin-angiotensin system (RAS) therapy to prevent adverse events, such as hyperkalaemia and acute renal failure. The authors concluded that increased laboratory monitoring could be cost-effective for patients starting RAS therapy, with a high risk of adverse events, but could not be recommended for all new patients. The methods were valid and should ensure that the authors’ conclusions are robust.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to examine the cost-effectiveness of extended laboratory monitoring during renin-angiotensin system (RAS) therapy, to prevent adverse events, such as hyperkalaemia and acute renal failure.

Interventions
Increased laboratory monitoring of RAS therapy, after medications were prescribed, was compared against the usual practice of conventional monitoring. The RAS therapy included angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs). Increased monitoring consisted of a pharmacy-led outreach programme that monitored serum potassium and serum creatinine levels for the first year of RAS therapy.

Location/setting
USA/primary care.

Methods
Analytical approach:
The analysis was based on a decision-analytic model, with three hypothetical populations: patients with diabetes, those with chronic kidney disease (CKD), and the general population. A time horizon of one year was selected for the costs and 10 years for the health benefits. The authors stated that the perspective of the health care payer was adopted.

Effectiveness data:
The data were from selected sources. The probability of a patient being included in a monitoring programme (monitoring uptake) was from a randomised trial. This was a key input for the analysis. The frequency of adverse events, due to ACE inhibitors and ARBs, was from a large health maintenance organisation (HMO) database, with approximately 450,000 members. The efficacy of monitoring in reducing adverse events was from an audit of charts of patients who experienced the adverse events, noting whether or not they had received monitoring, and based on expert opinion. Other data came from national reports and databases.

Monetary benefit and utility valuations:
The utility values were from a published economic evaluation of acute kidney injury.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and they were discounted at an annual rate of 5%.
Cost data:
The economic analysis included the costs of monitoring, laboratory tests, hospitalisation, emergency department visits, and out-patient visits. These costs were from US sources, such as the Healthcare Cost and Utilization Project (HCUP) and Medicare databases. A cost-to-charge ratio was applied, where relevant. The costs of malpractice litigation were included, using assumptions based on published studies. All costs were in US dollars ($).

Analysis of uncertainty:
A Monte Carlo simulation was used to generate estimates for the probabilistic sensitivity analysis, which focused mainly on two parameters: the effectiveness of a monitoring programme and the probability of poor outcomes in the population selected for monitoring. A threshold analysis was carried out on the risk of hospitalisation with each adverse event.

Results
Compared with standard care, the additional costs with increased monitoring were $24.3 in the overall population, $19.0 in the diabetes population, and -$7.0 in the CKD population. The QALYs gained were 0.000047 in the overall population, 0.0000070 in the diabetes population, and 0.000186 in the CKD population.

The incremental cost per QALY gained with increased monitoring was $521,818 in the overall population, and $269,727 in the diabetes population. The monitoring programme was dominant, as it was more effective and less expensive, in the CKD population.

At thresholds of $30,000 and $100,000 per QALY, the programme was cost-effective in less than 1% of simulations, for both the overall population and the diabetes population. For the CKD population, at $30,000 per QALY, it was cost-effective in 95% of simulations, and at $100,000 it was cost-effective in 99% of simulations.

Consistent findings were observed in the sensitivity analyses; the programme uptake rate was the most influential input. For example, assuming lower uptake (49% instead of 82% in the base case), the monitoring programme was no longer dominant for the CKD population and resulted in an incremental cost per QALY gained of $38,566.

Authors' conclusions
The authors concluded that increased laboratory monitoring could be cost-effective for new RAS therapy patients at a high risk of adverse events, but could not be recommended for all new patients.

CRD commentary
Interventions:
The comparators appear to have been appropriately selected to compare the standard care and the proposed extended monitoring. The authors noted that various monitoring approaches were available, but the one chosen was the most effective programme, as reported in the clinical trial that provided the key evidence.

Effectiveness/benefits:
The sources for the clinical data were of various validity and quality. The programme uptake was from a clinical trial that should have had high internal validity. The adverse events with usual practice were from a very large sample of HMO patients, which is likely to have been representative of the US context. The programme efficacy was from a chart audit and expert opinion, which were less valid sources, but extensive sensitivity analysis was conducted on this key parameter. QALYs were an appropriate benefit measure, as the adverse events could have an impact on quality of life and survival; little information was given on the source for the utility weights.

Costs:
The cost categories were relevant to the third party payer perspective as stated by the authors. Typical US sources were used for the total costs for each item, but the unit costs and resource quantities were not presented separately. The authors reported the impact of each resource, such as hospitalisation and out-patient visits, on the total costs for an adverse event. The costs were varied in the probabilistic sensitivity analysis. The price year was not explicitly reported. Discounting was not necessary, as the time horizon for the costs was one year.
Analysis and results:
The results were clearly presented and discussed; total and incremental findings were reported. The probabilistic analysis of the health and economic differences between groups showed that the results were robust. Alternative scenarios were considered in the deterministic analysis. The authors stated that the transferability of their findings to other settings depended on the dose intensity of the ACE inhibitors and ARBs, and on the rate of adverse events. Some assumptions were conservative against the monitoring programme.

Concluding remarks:
The methods were valid and should ensure that the authors’ conclusions are robust.

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