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 examine the cost-effectiveness of macrogol 4000 compared with lactulose for the treatment of chronic functional constipation in adult patients. The authors concluded that macrogol 4000 was a cost-effective treatment from the perspective of the British National Health Service. The study was based on valid methodology and was well reported. However, some limitations of the data sources might have affected the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The objective was to examine the cost-effectiveness of macrogol 4000 in comparison with lactulose for the treatment of chronic functional constipation in adult patients.

Interventions
The two osmotic laxatives were macrogol 4000 (two sachets per day) and lactulose (24mL per day).

Location/setting
UK/primary care.

Methods
Analytical approach:
This economic evaluation was based on a decision analytic model with a three-month time horizon. The authors stated that the analysis was carried out from the perspective of the British National Health Service (NHS).

Effectiveness data:
The clinical data came from an administrative database, namely The Health Independent Network (THIN) database, which contained long-term medical records representative of the entire UK population. The procedure to identify patients was described and there were 977 patients in each of the two treatment groups. They were well matched in terms of age, gender and the time between starting the new treatment and the previous laxative. The key clinical endpoint was the proportions of patients remaining on their laxative, discontinuing treatment, or switching to another laxative.

Monetary benefit and utility valuations:
The utility estimates were derived from a previous study that examined a sample of 308 members of the general public across the UK, using the standard gamble and time trade-off methods.

Measure of benefit:
The two summary benefit measures were the proportion of patients successfully treated over three months and quality-adjusted life-years (QALYs).

Cost data:
The health service costs were those of the two drugs, accident and emergency attendances, general practitioner (GP)
visits (at home and in the clinic), GP telephone consultations, hospital out-patient visits, laboratory tests, and practice nurse visits. The resource use data were derived from the THIN database. The unit costs and quantities of resources used were presented for all items. These costs were derived from the Drug Tariff, the British National Formulary, NHS Reference Costs, and the Personal Social Services Research Unit. All costs were in UK pounds sterling (£) and referred to 2004 to 2005 prices.

Analysis of uncertainty:
A probabilistic sensitivity analysis was undertaken by assigning probability distributions to all the model inputs. A deterministic sensitivity analysis was also carried out on the key inputs.

Results
The proportion of patients successfully treated over three months was 42% (95% confidence interval, CI: 38 to 46) with macrogol 4000 and 31% (95% CI: 27 to 37) with lactulose. The expected QALYs at three months were 0.213 (95% CI: 0.200 to 0.223) with macrogol 4000 and 0.210 (95% CI: 0.197 to 0.220) with lactulose.

The total three-month costs were £115 (95% CI: 98 to 132) with macrogol 4000 and £102 (95% CI: 86 to 119) with lactulose.

The incremental cost per additional patient successfully treated with macrogol 4000 over lactulose was £118 and the incremental cost per QALY gained was £4,333.

The probabilistic sensitivity analysis showed that macrogol 4000 had a 0.71 probability of being cost-effective at a threshold of £20,000 per QALY, a 0.78 probability at £30,000, and a 0.80 probability at £40,000. The deterministic sensitivity analysis indicated that the most influential model inputs were the probability of remaining on the initial laxative, the utility scores, and the number of GP home visits.

Authors’ conclusions
The authors concluded that, from the perspective of the NHS, treatment with macrogol 4000 was cost-effective compared with lactulose, for chronic functional constipation.

CRD commentary
Interventions:
The authors provided an explicit justification for their selection of the comparators: lactulose was chosen as the background comparator as it was the principle alternative treatment for chronic constipation in the UK and the most likely to be displaced by macrogol 4000, the newer product.

Effectiveness/benefits:
The authors used a large administrative database to derive the clinical data. This approach has several drawbacks mainly related to its retrospective nature, which limits the possibility of verifying the data accuracy, and the adaptation of administrative data to the purpose of the study. The authors stated that the patients were well matched according to the time between their last laxative prescription and starting the study drug. The baseline comparability of study groups with respect to other clinical and demographic factors was not demonstrated, except for age and gender. An advantage of such a large database is its ability to represent the general population in the UK. QALYs are a validated benefit measure, which allow cross-disease comparisons and capture the impact of the disease on the quality of life. The success rate is the natural endpoint of treatment and might be more relevant from a clinical viewpoint, but is a disease-specific measure. The authors pointed out that their definition of success might not have been precise because some assumptions were required to calculate the success rate from the database.

Costs:
The categories of costs and the sources used were consistent with the economic perspective. The resource use patterns were based on a large sample of patients and reflected real-world consumption of health services. However, the authors noted that the retrospective nature of the database might reduce the validity of the economic estimates. The transparency of the analysis was further enhanced by the detailed provision of data on unit costs, quantities of resources used, and the price year. The costs were derived from official sources in the UK.
Analysis and results:
The costs and benefits were synthesised using an incremental approach, which was appropriate given the higher costs and benefits of one treatment over the other. The issue of uncertainty was appropriately investigated. Details of the probabilistic sensitivity analyses were reported in depth. The findings were clearly presented and discussed. The decision model was clearly described with its transition patterns, structure, and assumptions.

Concluding remarks:
The study was based on valid methodology and was well reported. However, some limitations of the data sources may have affected the validity of the authors’ conclusions.

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Other publications of related interest

Christie AH, Culbert P, Guest JF. The economic impact of low dose polyethylene glycol 3350 plus electrolytes compared to lactulose in the management of idiopathic constipation in the UK. Pharmacoeconomics 2002;20:49-60.

Indexing Status
Subject indexing assigned by NLM

MeSH
Aged; Aged, 80 and over; Chronic Disease; Constipation /drug therapy /economics; Cost-Benefit Analysis; Female; Great Britain; Health Status; Humans; Lactulose /economics /therapeutic use; Laxatives /economics /therapeutic use; Male; Middle Aged; Polyethylene Glycols; Quality-Adjusted Life Years; Treatment Outcome

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