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 authors evaluated the cost-effectiveness of irbesartan treatment in end-stage renal disease in hypertensive patients with type 2 diabetes. They concluded that treatment with irbesartan improved outcomes and reduced costs. Despite some limitations to the clinical data, the methods appear to have been appropriate and comprehensive. The conclusions reached by the authors reflected the scope of their analysis.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to investigate the cost-effectiveness of irbesartan treatment in end-stage renal disease (ESRD) in hypertensive patients with type 2 diabetes.

Interventions
The three interventions were early irbesartan, late irbesartan, and a control regimen. The control regimen was conventional antihypertensive therapy that did not include angiotensin-converting enzyme inhibitors, angiotensin-2-receptor antagonists, and dihydropyridine calcium-channel blockers. Early irbesartan was given at 300mg per day and late irbesartan was given at 300mg per day, once overt nephropathy had developed.

Location/setting
UK/primary and secondary care.

Methods
Analytical approach:
This economic evaluation was based on a published Markov model (Palmer, et al. 2004, see 'Other Publications of Related Interest' below for bibliographic details), with seven health states to stimulate the progression from microalbuminuria to ESRD and treatment with dialysis. The time horizon was 25 years from a baseline age of 58 years. The authors stated that the UK National Health Service (NHS) perspective was adopted.

Effectiveness data:
The data on treatment efficacy and for transition probabilities were based mainly on two clinical trials: the Irbesartan in Reduction of Microalbuminuria-2 (IRMA-2) trial and the Irbesartan in Diabetic Nephropathy Trial (IDNT). Other data came from national registries and other published sources. The mortalities were country-specific. The key clinical inputs were the transition rates for ESRD with and without irbesartan.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The primary benefit measures were life expectancy and the number of life-years gained with the treatments. A 3.5% annual discount rate was applied to future benefits. The cumulative incidence of ESRD and the number of years the patients lived free of ESRD, were also reported.
Cost data:
The economic analysis focused on the incremental costs of irbesartan treatment and ESRD treatment, including dialysis or transplant and hospitalisation for comorbidities and complications. The costs of concomitant medications were assumed to be similar between treatments and were not included. The costs were derived from published literature and NHS databases. They were expressed in UK pounds sterling (£), for the price year 2002. All costs were discounted at a rate of 3.5%.

Analysis of uncertainty:
A second-order Monte Carlo simulation was used to generate the mean, standard deviation, and confidence intervals for the costs and benefits. Further sensitivity analyses were carried out by varying: the levels of urinary albumin excretion at which patients entered the state of advanced overt nephropathy; the transition probabilities between disease states; and the annual probabilities of death.

Results
The mean discounted life expectancies were 10.18 years with standard care, 11.00 years with early irbesartan, and 10.20 years with late irbesartan. The 25-year costs were £10,536 with standard care, £6,735 with early irbesartan, and £9,045 with late irbesartan.

Early irbesartan became cost-saving over standard care after 10 years of therapy and late irbesartan became cost-saving over standard care after six years of therapy. The costs and benefits were not combined in a cost-effectiveness ratio as irbesartan was the dominant strategy, as it was both more effective and less expensive.

The sensitivity analysis supported these base-case findings, in that none of the variations in the model inputs altered the conclusions of the primary analysis.

Authors’ conclusions
The authors concluded that treatment with irbesartan improved outcomes and reduced costs in hypertensive patients with type 2 diabetes, who were at risk of developing ESRD.

CRD commentary
Interventions:
The interventions were clearly reported, including the dosages. The selection of the interventions was justified and the study was thorough in its coverage of the interventions in its setting.

Effectiveness/benefits:
The main evidence on effectiveness came from two trials, but the selection of these trials was not justified which makes it difficult to ascertain if the best available evidence was used. The full details of the trials were not reported in this paper and a full assessment of their internal validity is therefore not possible. Life-years gained are a useful measure of benefit given the risk of death from disease progression, but relative quality of life outcomes should have been considered.

Costs:
The analysis of costs reflected the perspective, and the authors provided a justification for the exclusion of some cost categories. Little information on the sources of the data was provided and the details of the assessment of resource use were not reported. The unit costs and the resource quantities were not presented separately and a breakdown of the cost items was not reported. These characteristics will limit the possibility of replicating the analysis in other settings. The price year was reported, which will facilitate reflation exercises for other time periods.

Analysis and results:
The model structure, relevant details, and modelling assumptions were clearly reported. The results were also reported clearly. The dominance of irbesartan removed the need for a cost-effectiveness ratio to combine the costs and benefits. The issue of uncertainty was satisfactorily addressed, although the distributions used for the Monte Carlo simulation were not described. The authors outlined a number of possible limitations to their study and the impact of these on their
Concluding remarks:
Despite some limitations to the clinical data, the methods appear to have been appropriate and comprehensive. The conclusions reached by the authors reflected the scope of their analysis.

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MeSH
Antihypertensive Agents /economics /therapeutic use; Biphenyl Compounds /economics /therapeutic use; Cohort Studies; Computer Simulation; Costs and Cost Analysis; Diabetes Mellitus, Type 2 /complications /drug therapy /economics; Diabetic Nephropathies /complications /economics /prevention & control; Great Britain; Humans; Hypertension /complications /drug therapy /economics; Kidney Failure, Chronic /complications /economics /prevention & control; Middle Aged; Prognosis; Randomized Controlled Trials as Topic; Sensitivity and Specificity; Tetrazoles /economics /therapeutic use; Time Factors; Treatment Outcome