

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 a community-based screening and modified Diabetes Prevention Program (DPP) lifestyle intervention for individuals at high risk of type 2 diabetes and cardiovascular disease. The authors concluded that the modified DPP delivered in community and primary care settings was cost-effective and a sound investment. The methods were generally good and satisfactorily reported, as were the data sources and the results. The authors’ conclusions appear to be appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of a community-based screening and modified Diabetes Prevention Program (DPP) lifestyle intervention for individuals at high risk of type 2 diabetes and cardiovascular disease.

Interventions
A modified version of the DPP lifestyle intervention was compared with usual care, which was no screening and no intervention. The original DPP lifestyle intervention (The Diabetes Prevention Program (DPP) Research Group, 2002 and Knowler, et al. 2002, see ‘Other Publications of Related Interest’ below for bibliographic details) was modified for delivery to groups rather than to individuals. This modified DPP provided participants with instructions about diet and physical exercise, in 12 lessons (there were 16 in the original DPP) over 12 to 14 weeks. The intervention goals were to obtain and maintain a five to seven percent weight loss and to progressively raise activity levels to 150 minutes per week of moderately intense physical activity.

Location/setting
USA/primary care (local medical practice) and community care.

Methods
Analytical approach:
A Markov model, with a three-year time horizon, was developed to assess the cost-effectiveness of a community-based modified DPP for men and women aged 55 years. At the start of the model, participants without a history of diabetes were assessed for risk factors for diabetes and cardiovascular disease. The risk factors were a body mass index of 25kg/m² or more, with at least three components of metabolic syndrome; or overweight, with least two components of metabolic syndrome, a fasting glucose level of 100mg/dL to 109mg/dL, and a physician's referral to the intervention.

Those who had risk factors were eligible for the modified DPP intervention; those who did not have them were ineligible. The authors stated that a modified societal perspective was adopted and this excluded patient time costs.

Effectiveness data:
The authors selected the most appropriate estimates from the available evidence. The baseline cohort characteristics, probabilities of identifying risk factors by screening, and the modified DPP enrolment and retention rates were from two US community-based modified DPP reports. The authors excluded participants who started the modified DPP, but failed to return at 12 months for follow-up care. The metabolic resolution rates for enrolled patients with risk factors, for years two to three, and for non-enrolled patients without risk factors, for years one to three, came from the placebo arm of the DPP randomised controlled trial. Other probabilities, such as those of acquiring diabetes, progressing to
complicated diabetes, reducing risk factors, and death in each health state, were based on DPP or modified DPP studies or mostly from other US published sources.

Monetary benefit and utility valuations:
The health state utilities were based on data from published studies.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and they were discounted at an annual rate of 3%.

Cost data:
The direct health care costs included those of screening for the modified DPP and the personnel for each patient with or without risk factors. These were directly from the two US DPP project sites. Other costs for the modified DPP and for usual care, including the annual costs of diabetes and complicated diabetes, in patients with or without risk factors, along with cost multipliers for specific population subgroups, such as females and African Americans, came from an earlier US cost-effectiveness DPP study (Herman, et al. 2005, see ‘Other Publications of Related Interest’ below for bibliographic details). The price year was 2000 and the costs were inflated using the medical care component of the US Consumer Price Index. All costs were reported in US dollars ($) and future costs were discounted at an annual rate of 3%.

Analysis of uncertainty:
An extensive range of one-way sensitivity analyses and scenario analyses were conducted to assess the impact on the study results of variations in the model inputs, across ranges identified in the literature. Different assumptions for the continued resolution of metabolic syndrome were considered. Cost-effectiveness ratios of the univariate analyses were presented in a tornado diagram. Probabilistic sensitivity analysis, with all parameters varied simultaneously across their ranges, was conducted. The results of the probabilistic analysis were presented in a cost-effectiveness acceptability curve. The parameter distributions and their sources were reported.

Results
The costs in the base care were $2,528 for the modified DPP and $2,493 for usual care, an incremental cost of $34.50. The total QALYs were 2.40 for the modified DPP and 2.39 for usual care, an incremental gain of 0.01 QALYs. The incremental cost-effectiveness ratio of the modified DPP compared with usual care was $3,420 per QALY gained.

The univariate sensitivity analysis showed that the results were most influenced by variations in: the reduction in risk factors, the rate of intervention, the number of patients identified with risk factors, the diabetes incidence in patients with risk factors with or without the intervention, and the utilities for patients with risk factors. In all situations, the resulting cost per QALY was less than $20,000. Varying the discount rate from zero to 5% changed the results by less than $400 per QALY.

In scenarios with assumptions that were most unfavourable to the modified DPP (no difference in utilities in patients with risk factors between treatment groups, a higher risk of diabetes with the modified DPP, and a decrease in the benefit from the modified DPP compared with baseline) the cost per QALY gained increased and ranged from $56,200 to $95,400.

The probabilistic sensitivity analysis showed that at a willingness-to-pay threshold of $20,000 per QALY gained, there was a 78% probability that the modified DPP would be cost-effective over three years, and an 86% probability at a threshold of $50,000 per QALY gained.

Authors' conclusions
The authors concluded that the modified DPP delivered in community and primary care settings was cost-effective and a sound investment.

CRD commentary
Interventions:
The selection of comparators was appropriate as the proposed programme was compared with usual care. The interventions were clearly reported and described. The original DPP was not included, but might be a relevant comparator in some settings.

Effectiveness/benefits:
No systematic review to identify the relevant clinical evidence was reported, but the sources appear to have been appropriately selected as most of the data were from US studies (to reflect the authors’ context) and clinical trials. Two real-world modified DPP studies were used and included real-life factors, such as compliance and treatment drop-out, but only one was randomised and it is difficult to assess whether all the relevant clinical evidence was included. The authors pointed out the uncertainty around some estimates. For example, the assumptions for usual care came from the placebo arms of DPP trials, because there were no large scale randomised controlled trials comparing the modified DPP directly with usual care. QALYs were an appropriate benefit measure, given the impact of the disease on both survival and quality of life, but limited details of the methods used to derive the utility values were reported, which limits the generalisability of the results.

Costs:
The modified societal perspective, excluding patient time costs, appeared to include only the direct costs. The cost estimates were presented as category totals, without a breakdown of individual items and without a separate presentation of the resource use, which limits the generalisability and transferability of the findings to other settings. Most of the cost estimates and multipliers were from a single study that compared lifestyle changes, metformin, and placebo, as implemented in the DPP. It was unclear whether the population characteristics were the same and whether the intervention delivered in the modified DPP had different costs. The price year, discount rate, and inflation conversion were reported; the health care component of the Consumer Price Index might have been more appropriate.

Analysis and results:
The analytic approach was adequately described, with a diagram of the model, the health states, and the main patterns of care. The model cohort size was not reported and the reason for selecting the population age was not clear, but this might have been the average age of participants in the modified DPP trials. An incremental approach was appropriately used to synthesise the costs and benefits. The uncertainty was satisfactorily addressed in both deterministic and probabilistic sensitivity analyses. Some potential limitations were noted and might have underestimated the cost-effectiveness of the intervention. These were the short time horizon, the use of costs in 2000 US dollars, the inclusion of only the most common covariates to derive the annual probabilities, and the use of the placebo arms of the original DPP trials for some model assumptions and the comparison cohort for the modified DPP intervention.

Concluding remarks:
The methods were generally good and satisfactorily reported, as were the data sources and the results. The authors’ conclusions appear to be appropriate.

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Other publications of related interest
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