Alternative HbA1c cutoffs to identify high-risk adults for diabetes prevention: a cost-effectiveness perspective


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 investigated the cost-effectiveness of alternative cut-off levels for glycated haemoglobin, to identify individuals at high risk of diabetes and give them lifestyle interventions to prevent diabetes. The authors concluded that at a cut-off of at least 5.7%, prevention was cost-effective. The methods, analyses and results were comprehensive, but the validity of the clinical estimates, for progression and treatment effectiveness, was unclear, making it difficult to assess the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The aim was to examine the cost-effectiveness of alternative cut-off levels for glycated haemoglobin (HbA1c) in the blood, to identify adults (aged over 18 years) at high risk of diabetes, for its prevention.

Interventions
Ten cut-off levels of glycated haemoglobin, decreasing by 0.1% from 6.4% to 5.5%, were assessed. Each cohort of people with a level of glycated haemoglobin was compared with a cohort with a lower level, for example, 6.4% was compared with less than 6.4%. Those with the cut-off level were given prevention and those at the lower level received usual care.

Prevention was based on the high-cost Diabetes Prevention Program (DPP) study, or the low-cost Promoting a Lifestyle of Activity and Nutrition for Working to Alter the Risk of Diabetes (PLAN4WARD) study.

Location/setting
USA/primary care.

Methods
Analytical approach:
The analysis was based on a published Markov model (Herman, et al. 2005, see ‘Other Publications of Related Interest’ below for bibliographic details), with a lifetime horizon. The authors stated that a health care system perspective was adopted.

Effectiveness data:
The key clinical outcome was the reduction in diabetes risk. The characteristics of each cohort were based on the 1999 to 2006 National Health and Nutrition Examination Survey. The progression to type 2 diabetes was based on data from the Atherosclerosis Risk in Communities Study. Subsequent progression was based on the UK Prospective Diabetes Study. The main clinical estimates were from the two prevention studies (DPP and PLAN4WARD). The treatment effectiveness at three years was assumed to continue for the lifetime of the model.

Monetary benefit and utility valuations:
The utility estimates were derived from participants in the DPP. A cumulative model was used for the utilities for diabetes and any complications.
Measure of benefit:
Quality-adjusted life-years (QALYs) were the measure of benefit and they were discounted annually at 3%.

Cost data:
The direct medical costs included those of the glycated haemoglobin tests, the lifestyle interventions, annual screening tests, pre-diabetes care, diabetes care, and diabetes complications. Pre-diabetes costs were based on those in the DPP. Diabetes costs were calculated using a regression model. Medicare fee schedules and published studies were used to estimate the other costs. The price year was 2009 and all costs were reported in US $ and discounted annually at 3%.

Analysis of uncertainty:
One-way sensitivity analyses were performed on the key parameters, which were age, type 2 diabetes incidence, hypertension risk reduction, time before diagnosis, and diabetes risk reduction. Probabilistic sensitivity analysis was undertaken, using 500 Monte Carlo simulations. Normal distributions were applied for risk reductions and log-normal distributions were applied for cost inputs.

Results
Using the high-cost prevention, compared with a cut-off of 6.4%, a glycated haemoglobin cut-off of 6.3% cost an extra $16,000 per QALY gained. A cut-off of 5.5%, compared with 5.6%, increased the cost per QALY gained to $96,000 per QALY gained.

Using the low-cost prevention, lowering the cut-off from 6.0% to 5.9% cost an extra $24,000 per QALY gained, and this increased up to $70,000 per QALY gained, when decreasing the cut-off from 5.6% to 5.5%.

The sensitivity analyses showed that the results were most sensitive to changes in age, with higher ratios for treating only those aged 64 years or older, and in type 2 diabetes incidence. There was an 86% chance that a cut-off of 5.7% (compared with 5.8%) was cost-effective at a willingness-to-pay of $50,000 per QALY gained.

Authors’ conclusions
The authors concluded that at a glycated haemoglobin cut-off level of 5.7%, prevention was cost-effective, but 5.6% or lower could be cost-effective if the cost of prevention was reduced.

CRD commentary
Interventions:
The cut-off levels and interventions were well described. The incidence of individuals in each 0.1% level was based on data from American adults recorded in the National Health and Nutritional Examination Survey and this might be different in other settings.

Effectiveness/benefits:
Limited information was provided on the methods used to identify and select the data sources, which makes it impossible to determine if all of the best available evidence was used. The clinical effectiveness of the interventions was based on two published studies that were not described. No justification was provided to support the assumptions used in the model, such as the continuing effectiveness of prevention beyond the study period. The utility values were measured directly from the intended patient group; the methods used were not reported, but the references were given.

Costs:
The perspective was clearly defined and it appears that all the relevant costs were considered. The resource types were clearly presented and the measurement of the resources appears to have been reasonable. The unit costs for the tests and physician visits were appropriately based on national fee sources. The resource use and unit costs were not reported separately, which would have allowed the replication of the analysis for other settings. Other details, such as the price year, currency, and discounting, were provided.

Analysis and results:
The analytic approach appears to have been appropriate. Technical reports and additional information were provided in appendices. The incremental analysis was appropriate for determining the cost-effectiveness of prevention at different cut-off levels. The uncertainty in the results was tested, using appropriate methods, and the results were fully reported.
The authors discussed the implications of their findings for selecting a diagnostic threshold and the challenge of applying this. They highlighted the strengths and limitations of their analysis including: the profile and variation of the populations in the two prevention sources and some assumptions and simplifications that could have introduced bias.

Concluding remarks:
The methods, analyses and results were comprehensive, but the validity of the clinical estimates was unclear. It is therefore difficult to assess if the conclusions reached by the authors are reasonable.

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Other publications of related interest

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