The cost-effectiveness of primary prevention for non-insulin dependent diabetes mellitus
Segal L, Dalton A, Richardson J

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.

Health technology
Lifestyle and dietary advice, behavioural and surgical interventions for the primary prevention of non insulin dependent diabetes mellitus (NIDDM) as follows:

Programme 1 - work site group behavioural programme for overweight men;
Programme 2 - media programme for lifestyle change with community support;
Programme 3 - bariatric surgery for the seriously obese;
Programme 4 - intensive multidisciplinary behavioural and diet modification programme for the seriously obese;
Programme 5 - intensive diet and behavioural programme for women with gestational diabetes; and
Programme 6 - GP based lifestyle advice.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The target populations were either persons with impaired glucose tolerance (IGT) or a mixed population of individuals with IGT and persons with normal glucose tolerance (NGT). Other target populations were high risk ethnic groups, obese adults, and women with previous gestational diabetes.

Setting
Hospital, primary care, community, workplace, and media. The economic study was carried out in Australia.

Dates to which data relate
Mortality rates, adjusted for weight, were extracted from papers or reports published between 1980 and 1995. The transition probabilities were developed based on two key intervention studies, namely Eriksson et al (1991) and Long et al (1994), and expert opinions. The effectiveness data for the programme for women with gestational diabetes were based on the data collected at the Melbourne University/Mercy Women's Hospital for more than 20 years and from follow-up surveys conducted since 1982. The resource utilisation estimation was based on the programme descriptions and no date was specified in this regard. The price data referred to 1993-95.

Source of effectiveness data
Effectiveness data were derived from two clinical studies, a database from the Melbourne University/Mercy unit, literature reviews, expert opinions, and a Markov model.

**Link between effectiveness and cost data**
The costing was not performed on the same patient sample as that used in the effectiveness analysis. The costing was performed retrospectively.

**Study sample**
In the Swedish lifestyle modification study on overweight patients with early-stage NIDDM or IGT (Eriksson et al., 1991), there were four study groups consisting of two intervention groups (including 41 NIDDM patients at baseline in the NIDDM group and 181 IGT subjects at base line in the intervention-IGT group) and two control groups (including 79 IGT patients receiving normal care in the control-IGT group and 114 randomly selected NGT subjects in the control-NGT group). In the bariatric surgery study on 136 severely obese individuals (Long et al. 1994), there were 109 patients in the intervention group receiving bariatric surgery and 27 in the control group not receiving the intervention. The database from the Melbourne University/Mercy unit was the source of effectiveness data related to the programme for women with gestational diabetes. The study sample consisted of pregnant women with gestational diabetes, who were matched with invited controls. No more information was given about this study.

**Study design**
The Swedish lifestyle modification study (Eriksson et al., 1991), Long et al 1994 study, and the Melbourne study were non-randomised controlled trials with concurrent controls. The duration of the follow up in the Swedish study was 5 years. The corresponding figure in the Long study was 4.8 years. The rate of loss to follow up in the Swedish study was 2/41 in the NIDDM group; 20/181 in the intervention-IGT group; and 23/79 in the control-IGT group.

**Analysis of effectiveness**
It was not specified whether the analysis of the effectiveness results in each study was based on intention to treat or on treatment completers only. The key health outcomes in the Swedish study were weight loss at 5-year follow-up, fitness after 5 years (as measured by oxygen uptake), and the transition probabilities to different health states. The two IGT study groups were comparable in most parameters. The clinical outcome in the Long study was incidence of NIDDM (percent per annum). The change in BMI at 10 years follow-up (fell, no change, or increased) was the main health outcome in the Melbourne study.

**Effectiveness results**
Results for the NIDDM, intervention-IGT, control-IGT, and control-NGT groups were:

- Weight loss at 5-year follow-up: -2.0, -3.3, +0.2, and +2.0 kg, (P<0.0001);
- Fitness score: +14.5, +10.0, -4.9, and -9.0, P<0.03 for NIDDM and P<0.002 for IGT).

Transition rates after 5 years to NIDDM, IGT, and NIG state were:

- For the NIDDM group: 46.2%, 30.7%, and 21.1%;
- For the intervention-IGT: 10.6%, 37.3%, and 52.2%;
- For the control-IGT group: 21.4%, 42.8%, and 35.7%;
- For the control-NGT: 0, 7.1%, and 93%.

The incidence of NIDDM (% pa) was 0.15 for the intervention group versus 4.7 for the control group. Based on the results of the Long study and other studies, the five year transfer matrices for the surgical intervention were calculated.
The percentage of patients with gestational diabetes who experienced a fall in BMI whilst in the IGT or NGT group (n=145) was 89% against 11% for patients who developed NIDDM (n=50) (reference category). The corresponding percentages for the "no change in BMI" category were 73% and 27%, respectively (odds ratio, 2.91; 95% CI: 1.01 - 8.41). The corresponding values for the "increased" category were 67% and 33%, respectively (odds ratio, 3.85; 95% CI: 1.49 - 9.99). The transition matrices for this strategy were computed based on the results of the Melbourne study.

Clinical conclusions
The Swedish and Long studies revealed the effectiveness of the respective interventions in the primary prevention of NIDDM compared with normal care.

Modelling
A Markov model was employed to represent the expected progression between the health states of NIDDM, IGT, and NGT in order ultimately to estimate the cost-effectiveness of alternative programmes. Transition probabilities were estimated for each programme. The time period adopted in the transfer matrices was 5 years.

Outcomes assessed in the review
In the work place programme for males, the annual mortality, adjusted by metabolic state and applied for the successful participants in the intervention group, and the annual mortality adjusted for over-weight and applied for the unsuccessful participants in the intervention and control groups, were among the outcomes assessed in the review. Post-operative mortality and the effectiveness of bariatric surgery in terms of successful weight loss were among the other outcomes assessed.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Not reported.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
In the workplace programme for males, the annual mortality adjusted by metabolic state (% per annum) and applied for the successful participants in the intervention group ranged from 0.55 for participants aged 45-49 years with NIDDM to 2.32 for participants aged 65-70 years with NGT; the annual mortality adjusted for over-weight (r=r=1.2) (% per annum) and applied for the unsuccessful participants in the intervention and control groups varied from 0.66 for participants aged 45-49 years with NIDDM to 2.78 for participants aged 65-70 years with NGT. Post-operative mortality and the effectiveness of bariatric surgery in terms of successful weight loss were 1% and 87%, respectively.

Methods used to derive estimates of effectiveness
Estimates of effectiveness were also derived from expert opinions.

Estimates of effectiveness and key assumptions
The transition probabilities for the intervention group in workplace behavioural overweight males was assumed to be 0.010, 0.040 and 0.950 for the transition from NGT state to NIDDM, IGT, and NGT state, respectively. The corresponding values for the control group were 0.950, 0.040, 0.010. The value for the transition from NGT to NIDDM for the control group was 0.010. The assumed success rate and reduction in incidence of NIDDM for the workplace programme were 33% and 50%, respectively. The corresponding values for the intensive diet/behavioural programme for seriously obese and previous gestational diabetes were 33% and 70%-30%, and 33% and 50%, respectively. The success rate of the media-based programme was assumed to be 1% (0.1% in the sensitivity analysis) with a 50% rate of reduction in the incidence of NIDDM. In the GP-based programme, it was assumed that 20% of patients would achieve modest weight reduction/fitness enhancement; the successful intervention group was assumed to experience a 12.5% reduction in incidence of NIDDM. The success rate and reduction in incidence of NIDDM for the bariatric surgery were assumed to be 87% and 85%, respectively.

Measure of benefits used in the economic analysis
The measure of benefits used in the economic analysis were diabetes years prevented and life years gained. The benefit results per 100 participants were reported for two target populations, a population of persons with IGT and a mixed population (90% NGT and 10% IGT).

Direct costs
Costs were discounted. The resource quantities were not reported separately from the costs. The cost items included in each programme were reported separately. The programme costs were included in the cost analysis. The resource requirements of each programme in terms of natural units were estimated using the programme descriptions. The unit cost data were obtained from the published literature and were applied to the resource requirements of each programme in order to compute the programme costs. The cost calculations were performed from the perspective of a health care system. The price data referred to 1993-95. Expected health service savings due to general reduction in cardiovascular disease risk were not accounted for in the cost analysis. The costs of morbidity caused by surgery were not included in the cost analysis.

Indirect Costs
Not included.

Currency
Australian dollars (Aus$).

Sensitivity analysis
Sensitivity analyses were performed altering the values for programme cost, programme effectiveness, and the discount rate.
Estimated benefits used in the economic analysis
The greatest yield in terms of diabetes years prevented and life-years gained was from bariatric surgery with a total of 927 diabetes years prevented and a total of 423 life-years gained. The GP-based programme with 35 diabetes years prevented, and 64 life-years gained per 100 participants had the least effective performance. The duration of the benefit was assumed to be 25 years, beyond which the average life expectancy was the base of the calculations. The discount rate was 5%.

Cost results
The discount rate was 5%. The average cost per participant per programme was:

- workplace, Aus$195;
- intensive diet/behavioural for seriously obese, Aus$2,500;
- gestational diabetes, Aus$2,500;
- GP advice, Aus$420;
- bariatric surgery, Aus$13,300.

The total cost of the media campaign was Aus$2 million over 2 years. The costs of morbidity caused by surgery were not included in the cost analysis.

Synthesis of costs and benefits
Costs and benefits were combined using gross cost per diabetes year prevented, gross cost per life-year saved, net cost per diabetes year prevented, and net cost per life-year saved. In terms of gross cost per diabetes year prevented and gross cost per life-year saved, the workplace programme (for a population of IGT participants) was the most cost-effective strategy with a cost-effectiveness ratio of Aus$300 and Aus$500, respectively. The least cost-effective programme in terms of these two criteria was the GP advice, with a cost-effectiveness ratio of Aus$10,600 (gross cost per diabetes year prevented) and Aus$3,200 (gross cost per life-year saved), for a mixed population of NGT and IGT. The corresponding values for the bariatric surgery were Aus$3,200 (gross cost per diabetes year prevented) and Aus$12,100, for the IGT target population. In terms of net cost-effectiveness ratio, the workplace, intensive diet/behavioural programme for seriously obese (for the IGT target population), and media-based programme had net savings. The sensitivity analyses established the robustness of the results even to substantial variation in assumed parameter values.

Authors' conclusions
The authors concluded that "programs for the prevention of NIDDM can be highly cost-effective and may even be resource saving... All the behavioural modification programs are highly cost-effective or cost saving.”

CRD Commentary
The lack of randomisation may have weakened the internal validity of the effectiveness results. Also, little detail regarding the methodology of the literature review was provided in the paper. The fact that the estimation of resource requirements for each programme was based on expert opinion may also weaken the internal validity of the cost results.

Implications of the study
There is some evidence that preventive primary programmes for NIDDM based on workplace, community and media interventions are both effective and efficient, but further studies are necessary to resolve the uncertainty surrounding such conclusions.
Source of funding
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