Cost-effectiveness of use of the GlucoWatch Biographer in children and adolescents with type 1 diabetes: a preliminary analysis based on a randomized controlled trial

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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
The use of the GlucoWatch Biographer (GWB) to facilitate control of hypoglycaemia and hyperglycaemia in diabetic patients. The GWB is a watch-like device worn on the forearm that measures glucose frequently and automatically, displays glucose values and has user settable alarms. The device extracts sodium and other cations across the skin by the process of iontophoresis.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis; cost-utility analysis.

Study population
The study population comprised a hypothetical cohort of 10,000 children and adolescents with Type 1 diabetes and with poor glucose control, who had at least two glycohaemoglobin (HbA1c) values of at least 8% in the preceding 9 months. Patients with serious illnesses other than diabetes, or with known diabetic complications, were excluded.

Setting
The setting appears to have been secondary care. The economic study was conducted in the USA.

Dates to which data relate
The primary data on effectiveness and resource use were derived from a study published in 2003. The price year was 2002.

Source of effectiveness data
The effectiveness data were derived from a single study (see Other Publications of Related Interest) and authors’ assumptions.

Link between effectiveness and cost data
The costing was carried out prospectively on the same patients that were included in the effectiveness analysis.

Study sample
Power calculations, if conducted, were not reported. The method of sample selection was not described. Forty patients were enrolled in the study, 20 in each group. The mean age was 11.9 (+/- 3.1) years (range: 7 - 16) in the GWB group and 11.9 (+/- 3.3) years (range: 7 - 17) in the control group. The duration of diabetes was 7.1 (+/- 3.9) years (range: 2.3
- 14.4) in the GWB group and 5.5 (+/- 2.5) years (range: 2 - 9.4) in the control group. The GWB group contained 12 boys and 8 girls, while the control group contained 9 boys and 11 girls.

**Study design**
The following information was obtained from the published economic evaluation and the original clinical paper.

This was a randomised, controlled trial. The method of randomisation was not reported. The centres where the study was performed were not mentioned. The main analysis was likely to have been carried out at the Barbara Davis Center. The patients were initially treated for 3 months (intervention phase). During this time, the patients in the GWB group participated in a 15-hour accuracy study, were given the study device, and were trained to use the GWB, the AutoSensor (for more frequent use of the device), and the Precision Xtra meter (a conventional blood glucose meter). The patients in the control group used standard devices. Children in the intervention group were asked to bring their devices to the centre for downloading each week for 12 weeks. Children in the control group either brought or faxed their glucose data weekly and brought their meters once monthly for downloading. After the 3-month intervention phase, all patients were given the GWB for an additional 6 months. Two patients dropped out of the study. The HbA1c results were masked for care providers and families during the intervention phase. A medical monitor not involved in the study reviewed all HbA1c values.

**Analysis of effectiveness**
The basis for the analysis of the clinical study was not stated. It was unclear whether all the patients included in the initial study sample were taken into account in the effectiveness analysis. Several outcomes were reported in the original clinical paper. This published economic evaluation reported the average age when a complication occurred and the predicted lifetime cumulative incidence of complications. The complications included background retinopathy, proliferative retinopathy, macular oedema, blindness, microalbuminuria, albuminuria, end-stage renal disease, neuropathy, lower extremity amputation, first serious complication and first end-stage complication. Baseline comparability of the groups was not discussed in terms of demographics, but the authors stated that the HbA1c levels were comparable at baseline.

**Effectiveness results**
In summary, the outcomes improved for every complication with the use of GWB-assisted care. The absolute risk reductions under GWB-assisted care ranged from 1 to 20%.

After the intervention phase, patients in the GWB group had lower HbA1c levels than patients in the control group. This difference was maintained in the observation phase.

**Clinical conclusions**
The study showed that the use of the GWB significantly reduced the incidence of all complications. All patients wearing the device had significantly lower HbA1c values, and fewer insulin dose changes were observed in the intervention group.

**Modelling**
The authors used a published decision model (see Other Publications of Related Interest) to estimate the lifetime costs and benefits of using the GWB in patients with Type I diabetes. The original model compared intensive versus conventional therapy. It was then modified to reflect the patterns of care considered in the current study. The model was based on a Monte Carlo simulation and focused on the incidence of major complications (retinopathy, nephropathy and neuropathy). The health states considered were no retinopathy, background retinopathy, proliferative retinopathy, macular oedema, blindness, normoalbuminuria, microalbuminuria, albuminuria, end-stage renal disease, no neuropathy, neuropathy, and lower extremity amputation.
Methods used to derive estimates of effectiveness
The authors made some assumptions that were used in the decision model.

Estimates of effectiveness and key assumptions
It was assumed that the same frequency of GWB use would be required for the life of the cohort in order to achieve a persistent lowering of HbA1c levels. It was also assumed that the probabilities associated with the intervention reverted to standard probabilities (under usual care scenario) after the development of complications.

Measure of benefits used in the economic analysis
The summary benefit measures used in the analysis were years of life (YOL), quality-adjusted life-years (QALYs) and years free of a major complication. These were derived from the decision model. A 3% discount rate was applied since lifetime benefits were estimated. The model also estimated the predicted lifetime cumulative incidence of complications and the number of patients that would have to be treated to prevent one complication (number-needed-to-treat, NNT). The methods used to calculate the QALYs were not reported.

Direct costs
Discounting was relevant because the lifetime costs were assessed in the decision model. A 3% annual rate was applied. The unit costs were presented separately from the quantities of resources used. The cost categories included in the analysis were drugs, devices, treatment of complications and clinical care. The cost/resource boundary of the health service payer was used. Resource use was estimated from trial data, while the unit costs came from the study centre (the Barbara Davis Center), the Red Book and other sources. When actual prices were not available (e.g. the GWB), the authors made assumptions to estimate the costs. All of the costs were inflated to 2002 values using the consumer price index.

Statistical analysis of costs
No statistical tests of the costs were conducted.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses were conducted to evaluate the robustness of the cost-effectiveness ratios to variations in the model inputs. The model inputs investigated were the discount rate, age-specific mortality risk, cost of the AutoSensor, cost of the GWB, cost of medical care, HbA1c levels and limited use of the device (stop at 18 years of age). The ranges used were not reported.

Estimated benefits used in the economic analysis
The NNT ranged from 5 to prevent a case of proliferative retinopathy to 78 to prevent a case of amputation. The years free of complication ranged from 1.6 to 8 with the study device. The GWB led to an increase in YOL of 1.9 (undiscounted) and 0.44 (discounted), and 0.66 discounted QALYs.

Cost results
The estimated lifetime costs per patient were $185,825 in the control group and $226,314 in the GWB group. The cost-
The difference was $40,488.

**Synthesis of costs and benefits**
The incremental cost was $91,059 per YOL, $61,326 per QALY, and $9,930 per year free of major complications. The sensitivity analyses showed that the estimated cost per YOL and QALY were sensitive to variations in the discount rate, costs of the devices, HbA1c levels achieved during the intervention, and lifetime use of the device.

**Authors' conclusions**
The preliminary results from the economic evaluation of the GlucoWatch Biographer (GWB) were encouraging, as the use of the device improved patient outcomes.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. Standard care was selected to represent the usual pattern of care provided to patients with Type I diabetes. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness data were estimated from a randomised clinical trial, which was appropriate for the study question. There was very little reported about the internal validity of the clinical effectiveness data. The paper made reference to the original clinical paper (Chase et al., see Other Publications of Related Interest). It was therefore not possible to judge the internal validity of the effectiveness data from this paper.

**Validity of estimate of measure of benefit**
The main benefit measures were life expectancy and QALYs, which were appropriate to define the lifetime benefits of the study intervention. The use of QALYs appears to have been correct, as the disease affects both the quality and length of patient lives. Discounting was applied due to the long time horizon of the analysis. The use of QALYs and survival simplifies the comparison with the benefits of other health care interventions. However, details on the calculation of QALYs were not provided.

**Validity of estimate of costs**
The perspective adopted in the study was stated and only the direct costs were included in the analysis. However, a breakdown of the cost categories was not provided. The unit costs and the resource use data were presented separately and the price year was reported. This enhances the transferability of the cost analysis to other settings. Statistical tests of the costs were not carried out in the base-case, but extensive variations were performed in the sensitivity analysis and these identified the most relevant cost inputs. The source of the cost data was reported for only a few items.

**Other issues**
The authors did not compare their findings with those observed in other studies. They also did not address the issue of the generalisability of the study results to other settings. However, several sensitivity analyses were carried out. Caution is required when interpreting the results of the study due to the limitations of the analysis.

**Implications of the study**
The main implication of the study was that the use of the GWB improved complication-free survival and quality of life. However, the additional costs to obtain an extra benefit (in terms of either YOL or QALYs) appeared quite high in comparison with common thresholds used to evaluate the cost-effectiveness of health care interventions. Indeed, the authors stressed that their analysis was preliminary and a definitive evaluation of the GWB would require larger and longer trials.
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Other publications of related interest


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