Modem transmission of glucose values reduces the costs and need for clinic visits

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 electronic transmission of blood glucose levels and other diabetes data by modem technology, instead of clinic visits, in the management of Type 1 diabetes.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The patient population comprised male and female adolescents, aged 15 to 20 years, who had been diagnosed with Type 1 diabetes for at least one year and who attended a paediatric and young adult diabetes clinic. The patients were recruited for the study if they had GHbA1c levels of 7.0 to 13.0% and haematocrit levels of 20 to 55%. To meet the inclusion criteria, they also needed to be taking at least two insulin injections per day or using pump therapy, and be willing to perform at least two blood glucose tests per day. Patients were excluded if they had any significant diseases other than diabetes, or had plans to become pregnant during the next 2 months. Taking illegal drugs, planning surgery in the next 6 months, or being a ward of the state were also exclusion criteria. No one was excluded on the basis of ethnicity or gender.

Setting
The setting was the community and secondary care. The economic study was carried out in Colorado, USA.

Dates to which data relate
Both the effectiveness and cost data were derived from a single study carried out in one centre. However, the dates to which the data referred were not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively, on the same sample of patients that participated in the clinical study.

Study sample
The study sample consisted of 70 adolescent volunteers, both male and female, aged 15 to 20 years. The authors did not report any power calculations or method of sample selection, apart from the general inclusion and exclusion criteria.
The study sample was appropriate for the clinical study question since the study population was limited to adolescents with specific morbidity characteristics, as were those in the study sample. Both the intervention and control groups consisted initially of 35 patients each. However, 5 modem patients and 2 control patients were discontinued from the study due to non-compliance with the protocol, such as not transmitting glucose data (5 patients) and the inability to attend the 3-month clinic (2 patients). There was no significant difference in the discontinuation rate between the two groups (chi-squared, p=0.232). Therefore, 63 patients (30 in the modem group and 33 in the control group) completed the study.

**Study design**
The study was a randomised controlled trial that was carried out in a single centre. Each patient was randomly assigned to either the modem group or the control group. The method of randomisation was not stated. The duration of follow-up was 6 months. Apart from 7 patients who discontinued due to non-compliance, there was no further loss to follow-up. The outcome assessment was not blinded.

**Analysis of effectiveness**
The analysis of the clinical study was deliberately based on treatment completers only rather than "intention to treat" because the authors felt that, in the latter case, the costs for the modem group would have been falsely lowered. In addition, because follow-up data were not available for those who discontinued, the "last observation carried forward" was not applicable for statistical analysis.

The clinical outcomes assessed in the study were the GHbA1c values and the incidence of hypoglycaemia and diabetic ketoacidosis. Also evaluated were compliance with blood glucose testing and data transmission, and the degree of patient satisfaction. To estimate patient satisfaction, the participants were given a questionnaire at the end of the study, concerning overall satisfaction with the diabetes care received during the study. The patient groups were shown to be comparable in terms of their gender, age, duration of diabetes, and initial GHbA1c levels (p>0.05 for all parameters). The analysis was further adjusted to take patients with initial GHbA1c levels of at least 9% into consideration.

**Effectiveness results**
The mean baseline GHbA1c values were 9.0% (+/- 1.2) for the modem group and 8.9% (+/- 1.1) for the control group, (t-test, p=0.89). The GHbA1c levels significantly decreased in both groups during the 6 months, although the difference between the groups was not statistically significant. The mean, final GHbA1c value was 8.6% (+/- 1.7) for the modem group and 8.6% (+/- 1.2) for the control group, (t-test, p=0.96). There were also no significant differences between sub-groups with initial GHbA1c values of at least 9.0%.

The occurrence of diabetic ketoacidosis and hypoglycaemic events were also similar in the two groups. One patient in each group had several episodes of diabetic ketoacidosis, while another in each group had an episode of mild diabetic ketonuria that did not require hospitalisation.

Mild-to-moderate hypoglycaemia occurred, on average, 1.5 times/week in the modem group and 1.4 times/week in the control group, (t-test, p=0.71). No episodes of severe hypoglycaemia were reported in either group.

Test compliance was similar in the two groups, (t-test, p=0.91).

Both groups expressed high satisfaction with the overall diabetes care during the study, (p=0.81).

**Clinical conclusions**
There was no significant difference in GHbA1c values, incidence of hypoglycaemia and diabetic ketoacidosis, test compliance, or patient satisfaction between the modem and the control groups.
Measure of benefits used in the economic analysis
The authors demonstrated that the clinical outcomes assessed in the study were not significantly different between the two groups. Thus, no summary measure of benefits was used in the economic analysis and the analysis was based on cost differences only (i.e. cost-minimisation analysis).

Direct costs
The perspective adopted in the study was not stated, but the analysis included both the health service costs and non health care costs.

For the modem group, the direct costs were for the modem and computer, the training of a registered nurse to use the modem and transmission data (and subsequently train the patient or parents), staff, institutional overheads, and the patients’ phone expenses. The modem and computer cost was amortised over an average lifespan of 3 years with usage of 6 months. The staff costs were for health care professionals (mainly nurses) who downloaded data and had phone conversations. The quantities and the costs were analysed separately for the staff costs (the health professionals’ time was multiplied by the average wage). Modem, staff and patient costs were derived from actual data, whereas computer, overhead and training costs were estimated.

For the control group, the direct costs consisted of the aggregate cost of a 3-month clinic visit paid by the family or an insurance company (the range of time of a visit was reported), and additional patient costs such as parking, mileage, meals, hotel stay and babysitting. The patients were asked to complete an expense log that itemised their costs. It was not stated whether the costs of visits for the control group were based on actual resource use or reflected charges.

The dates to which the resources and prices for both groups referred were not reported. Discounting was not carried out, but this was appropriate as the costs were calculated a 6-month period.

Statistical analysis of costs
A range of health care costs and patient costs was provided for the control group only. An average cost per cost component was reported for the modem group. No results of statistical tests were presented in the cost analysis, apart from a comparison of the total costs in the two groups.

Indirect Costs
The indirect costs were included only in the modem group costs, to account for time the patients and their parents missed from school and work. Nevertheless, the time losses in the control group were also reported, although they did not lead to the calculation of indirect costs for this patient group. The time spent by the patient or parent in the modem group in training, talking to a care provider, and entering and transmitting data via the modem, was reported separately from the unit cost attached to every hour spent. The time was estimated from actual data. However, no explicit justification was given for the value chosen for the unit cost attached (which was common to both the patients and their parents). The dates to which the time and unit cost referred were not stated. Discounting was not relevant since the costs were estimated for a 6-month period.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
There was no statistically significant difference in benefits between the two interventions. See the 'Effectiveness Results' section.
Cost results
The total cost was $163.00 for the intervention group and $305 for the control group. The difference between these costs was statistically significant, (t-test, p<0.001).

The total costs referred to a 6-month period.

The costs of disease complications were not included in the study. These would probably not have affected the results, as diabetes-related incidents were not statistically different between the two groups.

Synthesis of costs and benefits
Not applicable. The difference in benefits between the two interventions was shown to be non statistically significant. Hence, the analysis focused on a comparison of the costs only.

Authors' conclusions
The use of modern technology for the biweekly transmission of blood glucose levels and other diabetes data to a health care provider was equally effective as current standard care of 3-monthly clinic visits, for a population of adolescents with Type 1 diabetes. The electronic transmission of data was also more cost-effective than standard care.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (3-monthly clinic visit) was justified by the fact that it represented current practice in the USA, as recommended by the American Diabetes Association. You should consider whether this reflects the current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a randomised clinical trial, which is the 'gold' standard method for the evaluation of effectiveness. The study sample was representative of the study population. The method of randomisation was not reported, hence it is difficult to rule out the possibility of selection bias. However, the two groups were shown to be comparable at analysis. It was reported that a statistical analysis was undertaken to take one parameter that might confound the results into consideration. No further adjustments for potential confounders were made. The analysis included outcomes for treatment completers only, as the authors felt that an "intention to treat" analysis would have introduced bias into the cost analysis. The number of participants and the length of follow-up were both very low, and this might affect the validity of the results.

Validity of estimate of measure of benefit
The statistical analysis showed that the study outcomes were not significantly different between the two groups. Thus, the economic analysis was categorised as a cost-minimisation analysis.

Validity of estimate of costs
Although the perspective was not explicitly stated, the analysis seems to have adopted a societal perspective. All the relevant health service and patient costs were included in the analysis. In addition, the authors elected to include the indirect costs. However, they estimated the indirect costs only for the modern group, and omitted any costs due to productivity losses borne by the control group. Nevertheless, since the control group still incurred higher total costs, this omission did not affect the conclusions. The costs and the quantities were reported separately for staff and patient costs in the intervention group only. For the control group, a range of costs was presented selectively. It is unknown whether the costs of clinic visits reflected charges or resource use. The choice of cost estimates such as overheads, training costs, and unit costs due to productivity losses was not justified.

No statistical analysis of the costs was performed, other than a comparison of the total costs in the two groups.
Discounting was not carried out, which was appropriate as the costs were incurred in 6 months. The dates to which the resources and prices referred were not reported.

**Other issues**

The authors made comparisons of their results for clinical outcomes with those from other studies and found them to be consistent. They stated that there were no other published studies examining the cost-effectiveness of the intervention. The issue of generalisability to other settings was not addressed. The study sample was limited to adolescents with diabetes of 7 to 8 years’ duration, and without co-morbidities, and this was reflected in the conclusions. Further, the authors were aware that the results might be partially affected by the study protocol, and that routine practice might result in different costs and outcomes. The study results appear to have been adequately reported and the conclusions represented the scope of the analysis.

**Implications of the study**

The authors suggested that future research is needed on the effectiveness of the intervention in patients with co-morbidities, as well as with newly diagnosed diabetes. They considered modem technology to be an effective practice that can solve physician shortages and space limitations, which are common problems in the USA in relation to diabetes care. However, the authors acknowledged that families who do not comply, or who need further education, might have to continue with the current practice.

**Source of funding**

Supported by a grant from Roche Diagnostics; grant M0-RR00069 from the General Clinical Research Centers Program, National Centers for Research Resources, National Institutes of Health (Bethesda, MD); and the Children's Diabetes Foundation (Denver, CO).

**Bibliographic details**


**PubMedID**

12716807

**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

Adolescent; Adult; Age of Onset; Blood Chemical Analysis /economics /methods; Blood Glucose /analysis; Colorado; Costs and Cost Analysis; Diabetes Mellitus, Type 1 /blood /economics; Female; Humans; Male; Modems /economics; Patient Selection

**AccessionNumber**

22003009792

**Date bibliographic record published**

31/05/2004

**Date abstract record published**

31/05/2004