Telecare of diabetic patients with intensified insulin therapy: a randomized clinical 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 technology studied was a telecare system for the monitoring and revision of insulin therapy. Patients transmitted their blood glucose readings to a diabetes centre using a modem interface. A physician then revised insulin treatment during scheduled telephone consultations with patients.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised insulin-dependent diabetic patients on a multiple injection regimen (basal insulin up to three times per day and short acting insulin for meal times). All patients had been on a structured diabetes education programme to enable them to calculate their insulin dose.

Setting
The setting was community and a diabetes centre. The economic study was carried out in Munich, Germany.

Dates to which data relate
No dates were reported.

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

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used for the effectiveness data. The costing study was undertaken retrospectively (after the effectiveness results were known).

Study sample
There were 46 subjects in this study: 30 in the telecare group and 16 in the conventional care group. The study sample was receiving insulin treatment appropriate to the study question. There were no explanations of how these subjects were selected or how the sample sizes were determined. The authors implied that patients were managed at a single diabetes centre. No power calculations were reported.
Study design
This was a single-centre, prospective, randomised controlled trial. The method of randomisation was not reported.
Patients were followed up for 8 months. No loss to follow-up was reported.

Analysis of effectiveness
Although not reported, data were presumably analysed on an intention to treat basis since there appears to have been no loss to follow-up. The primary health outcomes were the level of glycated haemoglobin (HbA1c), which is a parameter of metabolic control, and the frequency of hypoglycaemia. No statistical comparisons of groups (in terms of age, sex, etc.) or adjustment for confounding factors were performed at analysis.

Effectiveness results
The effectiveness results were as follows:

The HbA1c levels in the telecare group were 8.3% (baseline), 6.9% (after 4 months) and 7.1% (after 8 months).

The HbA1c levels in the conventional care group were 8.0% (at baseline), 7.0% (after 4 months) and 6.8% (after 8 months).

It was not stated whether these were mean, median or modal values.

There was no significant difference between the groups, \( p<0.01 \).

There was no significant difference in the frequency of hypoglycaemia between the two groups.

Clinical conclusions
Metabolic control with telecare, as measured by HbA1c levels and frequency of hypoglycaemia, is comparable to conventional outpatient care.

Measure of benefits used in the economic analysis
The HbA1c level after 4 and 8 months of observation was the measure of benefit.

Direct costs
The direct costs to the health service of the modem, telephone consultations and data transfer were included. Resource use and costs were reported separately. Costs were obtained from German telecommunication price lists. Data sources for the costs of the modem were not reported. No price years were reported. Discounting was not relevant, as the time period was less than one year.

Indirect Costs
The indirect costs included were travel costs and work stoppage (productivity losses). Resource use and costs were reported separately. The travel costs were derived from German public transportation price lists. Data sources for the costs of work stoppage were not reported. The cost boundary was that of the patient. No price years were reported. Discounting was not relevant, as the time period was less than one year.

Currency
Euros.

Sensitivity analysis
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
The authors reported no significant difference between telecare and conventional care on HbA1c levels and frequency of hypoglycaemia over the 8-month period. A survey showed that 90% of patients preferred telecare to conventional care.

**Cost results**
The annual costs per patient were Euro 389 (telecare) and Euro 1,037 (conventional care). An estimated Euro 648 per patient per year were saved with telecare.

**Synthesis of costs and benefits**
The authors did not undertake a synthesis of costs and benefits since telecare was a dominating strategy. Telecare was found to be cost saving, preferred by patients and was equivalent to conventional care in terms of metabolic control.

**Authors’ conclusions**
The authors concluded that telecare for insulin-dependent diabetic patients is cost and time saving and results in a similar level of metabolic control as conventional outpatient care.

**CRD COMMENTARY - Selection of comparators**
The comparator in this study was conventional outpatient care, which is assumed to be standard practice in the study setting. You, as a user of this database should compare this with standard care in your own setting, which may be in primary care rather than specialised care.

**Validity of estimate of measure of effectiveness**
The analysis was based on a prospective randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. A comparison of patient groups at analysis was not undertaken. The analysis of effectiveness was appropriate, although it is unclear whether the values of HbA1c were means. The estimation of benefits was obtained directly from the effectiveness analysis and the choice of estimate was justified. Patients acquired the skills needed to calculate their insulin requirements during a structured diabetes education programme but the authors did not discuss the impact of this programme on the effectiveness of telecare. This may have implications for the generalisability of the results to other countries and patient groups. The sample size of this study was relatively small, which may have led to the finding of no statistically significant difference in benefits.

**Validity of estimate of costs**
All categories of cost relevant to the perspective adopted were included in the analysis. Costs and quantities were reported separately. No statistical analysis of quantities was performed. A sensitivity analysis of prices was not conducted. The authors adjusted for protocol driven costs in order to generalise the findings to normal treatment. Attending a structured diabetes education programme may have influenced the time input of patients. The authors stated that, because telecare made it easy for patients to consult the clinical team, they did so more frequently. The effect on physician time was discussed but there was no mention of the impact on the time of other clinical professionals (e.g. nurses). The study lasted for only 8 months and the authors did not explain how they extrapolated the costs to annual figures.

**Other issues**
The authors mentioned the findings of similar studies and noted that it was not possible to compare them with the
findings of their study due to differences in study design. The authors noted that their estimates of physician time were comparable to those in another study. The issue of generalisability to other settings was not addressed. The authors did not present their results selectively. The study considered diabetics on intensive insulin and this was reflected in the authors' conclusions.

**Implications of the study**
The authors mention possible extensions to telecare including semi-automatic devices, internet technology and the inputting of insulin dose and ingested carbohydrate values.

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