Protocol for outpatient screening and initiation of continuous subcutaneous insulin infusion therapy: impact on cost and quality
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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 an outpatient screening protocol to identify patients with Type I diabetes who would be suited for continuous subcutaneous insulin infusion (CSII), and who would continue the treatment for two and a half years.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with Type I diabetes whose treatment programmes had been unsuccessful in achieving the desired glycaemic control.

Setting
The setting was a hospital-based outpatient diabetes centre. The economic study was conducted in the USA.

Dates to which data relate
Patient recruitment took place from March 1995 to March 1997, and the effectiveness and resource use data were gathered for 30 months. The price year was 2001.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not conducted. The patients were selected from a private endocrinology practice during the study period. A sample of 104 patients were enrolled and no external comparison group was considered. All of the patients were exposed to the outpatient screening protocol. Selection between those staying on CSII and those switching to other interventions occurred within the context of natural environment. The patients' demographics and clinical characteristics were not reported.
Study design
This was a pre-experimental one-group design with no external comparison group. The study was conducted in a single centre (a private endocrinology practice). The patients received three initial visits of one-to-one assessment/counselling with diabetes education staff (5 hours). At the third visit, a mock trial of CSII was initiated. Patients completed the presaline trial survey at the commencement of the mock trial and the postsaline survey once the trial had been completed. At the fourth visit, the patients were admitted to a hospital-based outpatient diabetes centre for 8 hours, where the transition from subcutaneous insulin therapy to CSII took place. The follow-up evaluation started after the fourth visit and lasted for two and a half years. It consisted of one-to-one assessment/counselling, telephone consultations, scheduled visits with an endocrinologist, and outcome assessment at 1, 3, 6, 12, 18, 24 and 30 months after the initiation of CSII. Eight patients were lost to follow-up.

Analysis of effectiveness
The analysis of the clinical study was limited to those remaining in the study. The primary health outcomes used in the analysis were screening protocol success, the safety profile of CSII, the change in haemoglobin A1C (A1C), and a psychosocial variable. Screening protocol success was evaluated as the proportion of patients who remained in the CSII protocol after its initiation. The psychosocial variable was evaluated using four instruments. The Short Form 36 (SF-36) included eight dimensions relating to physical functioning, role physical, bodily pain, general health perceptions, vitality, social functioning, role emotional, and mental health. The Presaline Trial Survey was administered before the onset of the mock saline trial and required the patients to score the importance of 18 lifestyle activities to their quality of life and the impact of CSII on such activities. The Postsaline Trial Survey was identical to the Presaline Trial Survey, but was administered at the conclusion of the mock saline trial. The Activities of Daily Living Survey was similar to the Presaline Trial Survey, but was administered at the follow-up assessment visits. The comparability of the study groups (those who used CSII and those who switched to multiple-dose injections) was not discussed.

Effectiveness results
Of the 104 patients included in the initial study sample, 6 withdrew prior to the first visit, 9 withdrew after the first visit, one died, 16 left the study after the second visit, and 12 left after the third visits. Thus, before the CSII was initiated, the screening protocol was effective in excluding 44 patients who would have left the intervention.

Of the remaining 60 patients who received CSII, 3 moved to another area of the country and were lost to follow-up while 2 switched to multiple-dose injections. Thus, the screening protocol failed to detect only 2 patients who would have left the CSII intervention.

In terms of the safety profile, only one patient out of 60 receiving CSII experienced an episode of hypoglycaemia that required the assistance of another person during the critical 4-day transition period.

At baseline, there was no statistically significant difference in the average A1C levels. At the quarterly follow-up assessments, the average A1C levels was lower for those who initiated CSII (7.06%) than those who withdrew from screening (7.36%), (P=0.003).

For the SF-36, there were significant improvements in some parameters, such as general health, physical pain and energy, over the 30-month period.

Positive changes were observed also with the Presaline Trial Survey, the Postsaline Trial Survey and the Activities of Daily Living Survey. In particular, in terms of eating, working, sleeping, bathing/showering and sexual intimacy, which were perceived as the factors having the greatest impact on quality of life.

Clinical conclusions
The effectiveness analysis showed that the outpatient screening protocol was effective in identifying patients suited for CSII and improved the patients’ quality of life.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore conducted.

Direct costs
The costs observed in the present study were compared with those observed in the DCCT. Discounting does not appear to have been conducted, although it was relevant since the costs were incurred over 30 months. The unit costs were reported separately from the quantities of resources used. The health services included in the economic evaluation were screening, CSII initiation and follow-up. The cost/resource boundary was that of the health care system. Resource consumption was estimated from data referring to the same sample of patients as that used in the effectiveness study. The source of the unit costs was not explicitly reported, but the authors stated that the prices used in the study represented current costs of the services in the urban Midwestern United States. The price year was 2001.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included in the economic evaluation.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not conducted.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The cost of screening per patient was $517.50, the cost of the CSII initiation was $225, and the cost for follow-up was $1,689. Thus, the total cost per patient was $2,431.50.

The total costs per patient in the DCCT were $8,265 ($0 for screening, $2,900 for CSII initiation, and $5,365 for follow-up). The net cost avoidance with the outpatient screening protocol was $1,639.82 per patient screened.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
The outpatient screening protocol was effective in identifying patients with Type I diabetes who would initiate continuous subcutaneous insulin infusion (CSII) and continue for more than two years. The programme was associated with cost-savings when compared with other protocols, such as that reported in the Diabetes Control and Complication Trial (DCCT).

CRD COMMENTARY - Selection of comparators
The health intervention used as the comparator in the study was multiple-dose injections, which represented the standard procedure for insulin administration. Thus, it appears to have been appropriate. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a pre-experimental one-group design with no external comparison group. The study sample was unselected and appears to have been representative of the study population. The length and loss to follow-up were reported. The analysis of the clinical study was limited to those who remained in the study. Patient allocation to study groups occurred within the context of natural environment. The authors acknowledged that this could have led to selection bias, but stressed that selection had to be spontaneous to evaluate the effectiveness of the screening protocol. The comparability of the study groups was not discussed. These issues tend to limit the internal validity of the effectiveness study.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
The perspective adopted in the study appears to have been that of the health care system, and all relevant categories of costs appear to have been included in the analysis. The economic analysis appears to have been conducted appropriately and details were provided on each step of the calculation. The unit costs and the resources used were reported separately and the price year was reported. These factors enhance the reproducibility of the study results in other settings. The source of the cost data was not clearly stated. The cost estimates were specific to the study settings. No statistical analyses were conducted.

**Other issues**
The authors compared their findings with those reported in the DCCT study. However, they did not conduct any further comparisons. The issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were conducted. These facts may reduce the external validity of the analysis. The study referred to patients with Type I diabetes and this was reflected in the conclusions of the analysis. The authors acknowledged that the study design may have been inappropriate for the study question.

**Implications of the study**
The study suggests that an outpatient screening protocol for the identification of patients with Type I diabetes suitable for CSII represented a safe, effective and cost-saving option. The authors stated that the study results should encourage broader application and reimbursement of CSII therapy for appropriately screening candidates.

**Source of funding**
Funded by the Blue Cross Blue Shield of Michigan Foundation.

**Bibliographic details**

**PubMedID**
12224200

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Activities of Daily Living; Ambulatory Care /organization & administration /psychology; Clinical Protocols /standards; Cost-Benefit Analysis; Diabetes Mellitus, Type 1 /drug therapy /metabolism /psychology; Follow-Up Studies; Hemoglobin A, Glycosylated /metabolism; Humans; Hypoglycemic Agents /administration & dosage; Infusion Pumps; Insulin /administration & dosage; Life Style; Mass Screening /organization & administration; Nursing Assessment /methods /standards; Patient Selection; Quality of Life; Surveys and Questionnaires /standards

**AccessionNumber**
22002001383

**Date bibliographic record published**
30/11/2003

**Date abstract record published**
30/11/2003