Medication adherence and the associated health-economic impact among patients with type 2 diabetes mellitus converting to insulin pen therapy: an analysis of third-party managed care claims data

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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 study examined the use of an insulin analogue pen device for the administration of insulin to patients with Type 2 diabetes mellitus. The comparator treatment was to take the insulin by injection (vial/syringe).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adults with a diagnosis of Type 2 diabetes (International Classification of Diseases, 9th Revision, Clinical Modification, code 250.xx, excluding Type 1 subcodes) whose treatment was converted from conventional human or analogue injection to a pre-filled insulin analogue pen. The patients had to have data for at least 6 months before the changeover date and at least 2 years after the changeover date.

Setting
The setting was not explicitly reported. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use evidence dated from 2001 to 2005. The price year was 2005.

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

Link between effectiveness and cost data
The same patients provided the cost and effectiveness data. The costing was carried out retrospectively.

Study sample
No power calculations were reported. All patients in the 57 managed care plans in the USA who met the inclusion criteria, and who switched to an analogue pen between July 2001 to December 2002, were included in the study. There were 1,156 patients in the study and, as it was a longitudinal study, all patients were in both the intervention and control groups. A total of 595 patients had used human insulin and 561 had used an insulin analogue before the switchover from vial/syringe to insulin pen.
Study design
This was a multi-centre, longitudinal, within-group comparison study in which the patients were followed up until 30 April 2005 or until they discontinued using the insulin analogue pen. The duration of follow-up was 2 years after the switchover.

Analysis of effectiveness
The basis of the analysis was treatment completers only, in that only patients who had records for 2 years were included in the study although some of them will not have continued treatment. The primary health outcome used was the likelihood of experiencing a hypoglycaemic event which resulted in various kinds of health care utilisation: visit to the emergency department (ED), hospital inpatient stay, physician visit, outpatient visit and "other". Also assessed as a factor influencing health outcomes was the medication possession ratio (MPR). The MPR measures the proportion of time that the patient had a supply of the medication. The proportion of patients with an MPR of at least 80% was also used. One of the findings of the study was that the MPR was strongly negatively associated with the likelihood of experiencing hypoglycaemic events. There were no data on comparability of the groups at baseline since this was a longitudinal study.

Effectiveness results
After adjusting for the differing lengths of follow-up, the switch to the insulin analogue pen meant the likelihood of experiencing a hypoglycaemic event was reduced by 50% (odd ratio 0.50, 95% confidence interval: 0.37 to 0.68; p<0.05).

The changes in hypoglycaemic events occurred at the same time as the mean MPR increased from 62% (SD=28) to 69% (standard deviation, SD=33), (p<0.01).

The proportion of patients with an MPR of at least 80% rose from 36.15 to 54.6%, (p<0.01).

Clinical conclusions
The authors concluded that the incidence of hypoglycaemic events decreased and that the MPR improved as a result of the switch to the insulin analogue pen.

Modelling
A Poisson multivariate model was used to assess significant causes of hypoglycaemic events after the patients switched to the insulin analogue pen device.

Measure of benefits used in the economic analysis
No summary measure of benefit was used so the authors, in effect, carried out a cost-consequences analysis.

Direct costs
No discounting was carried out. The quantities and the costs were not analysed separately, although the number of ED visits and the length of stay in hospital were given. The costs of ED visits, outpatient visits, inpatient hospital stays, physician visits and pharmacy were measured. The costs were based on actual data obtained from the PharMetrics database, which contains medical and pharmacy claims from insured patients. The price year used was 2005.

Statistical analysis of costs
No statistical analysis of the costs was carried out.
Indirect Costs
No indirect costs were estimated.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
The costs were annually adjusted. The mean cost per patient was $16,359 (SD=23,715) before the change and $14,769, (SD=18,831) after, a difference of -$1,590 (SD=3,442).

The mean cost per patient attributable to hypoglycaemia was $1,415 (SD=2,556) before the change and $627 (SD=993) after, a difference of -$788 (SD=1,228), (p<0.01).

Other costs attributable to diabetes changed from $8,827 before the change to $8,227 (SD=9,117) after, a difference of -$600 (SD=945), (p not significant).

The length of time for which costs were used to calculate the average annual cost after the changeover varied between patients. The maximum time was 3.75 years.

The costs of adverse effects were dealt with in the costing.

Synthesis of costs and benefits
The costs and benefits were not combined as the study was a cost-consequences analysis.

Authors' conclusions
Changing from the administration of insulin by a vial/syringe to an analogue pen improved adherence, lowered the frequency of hypoglycaemic events and reduced treatment costs.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (i.e. use of a vial/syringe) was implicitly justified as it has represented normal practice in the past in the authors' setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The source of the effectiveness data was a single within-group comparison study. The records of patients who could provide data for 6 months before the intervention and 2 years after the intervention were evaluated. This was not ideal as other changes could have occurred over time. Also, the study only used data from the insured population in the USA and there were no complete data for patients if they stopped being insured after the 2 years necessary to qualify. As the study examined the insured population, the study sample was representative of that population, but it might not have been representative of all Type 2 diabetes mellitus sufferers in the USA. The comparability of the two patient groups was not an issue as this was a within-group comparison study. However, the authors did not show that the patients were comparable at the beginning of the 6-month period before the changeover and at the beginning of the period after the
changeover. Apart from these drawbacks, the analysis of effectiveness was handled credibly.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The health benefits are therefore those associated with the effectiveness outcomes.

**Validity of estimate of costs**
Given the cost perspective adopted (i.e. that of the medical insurance system), all the relevant cost categories were covered. The authors pointed out that some insulin-related products are available over the counter and these will not have been included in the cost estimates. The costs and the quantities were not reported separately, although some information was provided on the quantities of resource use. The resource use quantities were taken from a single study, while the prices were taken from the authors' setting. No other sources of prices were used. No statistical or sensitivity analysis of the quantities or prices was carried out. Discounting was not undertaken even though the costs were incurred over more than 2 years. Charges were used to derive cost data. The price year was 2005.

**Other issues**
The authors made appropriate comparisons of their results with the findings from other studies. They acknowledged that their results may not be generalisable to all health plans or geographic regions. The authors did not present their results selectively and, given the limitations of the study, their conclusions reflected the scope of the analysis. The authors reported, as a limitation of their analysis, that the switchover to the analogue pen may not always have been an exogenous event, but may have been precipitated by the high number of hypoglycaemic events before the switchover. The authors are aware that using claims data may produce some selection bias as the study sample will not be representative of all diabetes sufferers in the USA.

**Implications of the study**
The authors concluded that switching to an insulin analogue pen is associated with a reduction in hypoglycaemic events, which occurred concurrently with improved adherence and with lower treatment costs. They recommended further research to assess the effect of differences in health plan design on the changeover to an insulin analogue pen, as well as more research to identify the causal factors associated with improved adherence.

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**Other publications of related interest**
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