**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.

**CRD summary**
The aim was to assess the long-term cost-effectiveness of biphasic insulin aspart 30 (BIAsp30) compared with human insulin, for patients with type 2 diabetes mellitus that was poorly controlled on human insulin, in South Korea. The authors concluded that BIAsp30 appeared to be cost-effective for these patients. These conclusions do not account for the uncertainty surrounding the clinical effectiveness estimates that were based on observational data.

**Type of economic evaluation**
Cost-effectiveness analysis, cost-utility analysis

**Study objective**
The aim was to assess the long-term cost-effectiveness of switching to biphasic insulin aspart 30 (BIAsp30) from human insulin, for patients with poorly controlled type 2 diabetes mellitus in South Korea.

**Interventions**
Patients with type 2 diabetes that was inadequately controlled by treatment with human insulin were switched to BIAsp30. This was compared with continuing treatment on human insulin. Either treatment was given as monotherapy or in combination with oral antidiabetic drugs.

**Location/setting**
Korea/secondary care.

**Methods**

**Analytical approach:**
A published and validated diabetes state-transition model (Palmer, et al. 2004, see ‘Other Publications of Related Interest’ below for bibliographic details) was used to estimate the clinical effectiveness and costs of switching to BIAsp30 from human insulin. A hypothetical cohort of 1,000 patients were modelled, using the characteristics of a subgroup of patients, who were on human insulin at the start, from the South Korean part of the Physician’s Routine Evaluation of Safety and Efficacy of NovoMix® 30 Therapy (PRESENT) study (Khutsoane, et al. 2008, see ‘Other Publications of Related Interest’ below for bibliographic details). The time horizon was 30 years and the authors stated that a third-party payer perspective was taken.

**Effectiveness data:**
The effectiveness data were a combination of changes in HbA₁c, hypocalcaemia event rates, and BMI, from the subgroup of the South Korean PRESENT study. This was a one-arm observational study, in which patients who were not adequately controlled on their existing treatment were switched to BIAsp30. The key outcomes were life expectancy, quality-adjusted life-years (QALYs), and complications.

**Monetary benefit and utility valuations:**
Not described.

**Measure of benefit:**
The measure of benefit was QALYs gained and the benefits were discounted at an annual rate of 5%.
Cost data:
The direct costs of treatment, patient management, and diabetes-related complications were included. The cost data were from a combination of IMS Health data and a cost questionnaire sent to a sample of 54 South Korean clinicians. The costs were reported in Korean won (KRW) for the price year 2007. They were discounted at an annual rate of 5%.

Analysis of uncertainty:
A series of one- and two-way sensitivity analyses was performed to assess the impact of several key parameters on the results and a probabilistic sensitivity analysis was also performed.

Results
There was an increase in life expectancy of 0.15 years (SD 0.18) with BIAsp30 (8.62 years) compared with human insulin (8.47 years). The increase in QALYs per patient was 0.30 (SD 0.12) with BIAsp30 (5.68 QALYs) compared with human insulin (5.38 QALYs).

The mean total costs with BIAsp30 (KRW 12,214,835) were KRW 1,776,855 more per patient than with human insulin (KRW 10,437,982).

The discounted incremental cost-effectiveness ratio for BIAsp30 compared with human insulin was KRW 5,916,758 per QALY gained. The cost-effectiveness threshold, based on gross domestic product per capita, was KRW 25 million per QALY.

Authors’ conclusions
The authors concluded that BIAsp30 appeared to be cost-effective for patients with poorly controlled diabetes, when treated with human insulin.

CRD commentary
Interventions:
The intervention was well described, and the comparator was appropriate as it reflected the usual care in the study setting. These comparators are likely to be relevant to other study settings.

Effectiveness/benefits:
The source of the effectiveness data, the PRESENT study, was well described, referenced, and relevant to the study setting and population. The PRESENT study was an observational study in which those patients whose diabetes was improperly controlled on human insulin were switched to BIAsp30. This implicitly assumes that if the patients remained on human insulin, nothing would change. This design is open to bias and there was no evidence that the authors systematically searched the literature for other relevant clinical studies. The sources used to derive the utility estimates were not given and neither were the instrument used and the sample population. The time horizon of 30 years should have been adequate to capture the differences in health outcome between the two treatments.

Costs:
The authors stated that the perspective was that of the third-party payer and they appear to have included all the relevant costs. The cost data were fully described, with the relevant cost adjustments.

Analysis and results:
The analytic approach was satisfactorily reported, but no diagram was presented and this would have aided comprehension. An incremental analysis was properly conducted to determine the cost-effectiveness of the two strategies. The issue of uncertainty was appropriately addressed, with both univariate and probabilistic sensitivity analyses being conducted. The results of both the base case and the sensitivity analyses were extensively reported and the authors highlighted the strengths and limitations of their analysis.

Concluding remarks:
The authors’ conclusions do not account for the uncertainty surrounding the clinical effectiveness estimates that were based on observational data.
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