INTRODUCTION

- The purpose of the evaluation was to compare the relative cost-effectiveness (cost utility) of insulin glargine in the UK for the treatment of people with Type 1 diabetes mellitus (T1DM) through either reduced hypoglycaemia or through improved glycaemic control using pooled data from the Phase III clinical trials programme.

MODELLING APPROACH AND MODEL

- This evaluation was undertaken within the context of the UK National Health Service (NHS), and used the NHS as its prospective. A discrete event stochastic simulation model was developed to compare a cost utility analysis (CVA) to ascertain the cost per quality adjusted life years gained (QALYs gained) using insulin glargine compared to NPH insulin.

- The model simulates a cohort of 10,000 subjects over 40 years in yearly increments. Figure 1 details the model flow diagram. Transition functions are used to model disease progression through five vascular endpoints and two glycemic complications. Microvascular complications were based on the simplified model of disease progression previously used by Palmer and colleagues. Fatal and non-fatal cardiovascular events were predicted using the Framingham risk equations.

- The five vascular complications predicted in the model were end-stage renal disease, 1st acute myocardial infarction, stroke/CV death, nephropathy and neuropathy. Stroke/CV death and nephropathy were further stratified (symptomatic, severe, ruptured carotid). The model had the ability to assess the economic impact of each reduction in hypoglycaemia or an improvement in glycaemia or both of these at the same time.

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- The rates of severe, nocturnal, and symptomatic hypoglycaemia were drawn from the DCCT trial, the Cardiff Hypoglycaemia Survey, and those reported by Pampolnelli and colleagues.

- Populations, Costs and Utilities

  - The baseline characteristics of the primary prevention cohort from the DCCT study were used to generate the cohort profiles. Mean age was 27 ± 5.5 years male.
  - Utility values associated with vascular endpoints were drawn from the Health Outcomes Data Repository (HOVER) study. Utility associated with hypoglycemic events was predicted via statistical models that related the frequency and severity of hypoglycaemia to fear of hypoglycaemia, and subsequently to changes in health-related utility.
  - Costs were calculated from UK £2005 prices. Costs and benefits were discounted annually at 3.5%

MAIN COMPARISON SCENARIOS

- Comparison scenarios were based on differences in hypoglycaemia only and/or HbA1c only.
- Table 1 lists the reductions in severe, nocturnal and symptomatic rates for all T1DM studies and pre-registration TIDM studies (scenarios 1 and 2 respectively). Scenarios 3 and 4 model the absolute % HbA1c reductions observed in ≥5 month TIDM studies and pre-registration TIDM studies respectively.

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- In the first three scenarios there was an overall difference of 662,841, and 1,325,682 episodes of nocturnal hypoglycaemia and a difference of 76,287, and 85,895 episodes of severe hypoglycaemic for scenarios 1 and 2, respectively (Table 2).
- In scenarios 3 and 4, where HbA1c differences were also considered, there was a difference of 944 and 2,739 microvascular events, respectively (Table 3). In these scenarios there were less macrovascular complications and less hypoglycaemia in the NPH group as a result of differential survival.

- Total treatment costs over the simulation period when using NPH were less than glargine due to the difference in unit cost of insulin; with differences in discounted total costs were £1,359,426, and £1,335,572 for scenarios 1 and 2 respectively. Under the same conditions in the number of QALYs gained by using glargine was 12,4, and 140 respectively. Therefore, under scenarios 1 and 2 when comparing glargine versus NPH the overall cost per QALY was £10,493, and £6,492 respectively.

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