

Correlating cost-effectiveness output with patient-level data input via the IMS CORE Diabetes Model (CDM)

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Introduction

The use of patient-level data (PLD) offers significant advantages over modeling cohorts in health economic models. Individual patient-level risk can be calculated easily that preserves the covariance structure associated with the overall cohort.

Sub-group analysis is an important component of any cost-effectiveness (CE) evaluations and the analysis of PLD output by a CE model also offers the potential to better understand patient profiles associated with greatest health economic benefit.

The objective of this study was to contrast the application of an average treatment efficacy profile compared to patient-level treatment efficacy in assessing the CE of insulin glargine (IG) versus Neutral protamine Hagedorn (NPH) in Type 2 diabetes mellitus (T2DM) using an established T2DM simulation model.

Methods

This study used the IMS CORE Diabetes Model (CDM) [1], a validated and established diabetes model, to evaluate the CE of switching to IG from NPH using published effectiveness data from a large case-control population based study [2].

The effects on HbA1c of changing from NPH to IG were extracted from this study. Average HbA1c reduction after switching from NPH to IG was -0.18% and weight gain was 0.5kg. Table 1 shows the sex, body mass index (BMI) and HbA1c at baseline-adjusted values employed.

A PLD extract was obtained from NHANES and the CE of IG versus NPH assessed applying (a) overall mean treatment effects (MTE) and (b) baseline HbA1c, BMI and sex adjusted treatment effects (ATE).

The annual diabetes specific therapy cost was £573 (IG) versus £320 (NPH) with (2012 UK£) costs of complications applied.

The CDM was run over a lifetime with both costs and benefits discounted at 3.5%.

Table 2) Summary statistics for NHANES patient-level data extract (n=1,859)

Variable	Mean	SD
Age (years)	63.6	12.1
Male (%)	53	
Duration (years)	9.5	8.5
Smoker (%)	16	
HbA1c (%)	7.4	1.8
SBP (mmHg)	134.9	22.0
Cholesterol (mg/dl)	195	50.5
HDL (mg/dl)	47.9	13.8
BMI (kg/m ²)	30.6	6.3

Results

For the MTE and ATE scenarios, the incremental cost-effectiveness ratio (ICER) was £28,925 and £57,279 respectively.

For MTE scenario, 765 (41.1%) of subjects were CE at the £20,000 willingness to pay (WTP) and 47 IG subjects (6.1%) were both cost saving with increased health benefit.

Using ATE, 525 (28.2%) were CE at the £20,000 WTP threshold with 164 (31.2%) of IG subjects identified as both cost saving with increased health benefit.

Using the ATE analysis, analysis of PLD showed an odds ratio (OR) of being both cost saving with greater health benefit was significantly associated with age, OR=0.89(0.87-0.93) and baseline HbA1c, OR=6.11 (4.64-8.03) (Table 4).

Table 4) Logistic regression coefficients predicting the likelihood of cost saving and additional health benefits in those switching from NPH to IG

	Coefficient	SE	z value	P(> z)
Intercept	-13.913	1.691	-8.667	<0.001
Age	-0.111	0.016	-7.086	<0.001
HbA1c	1.822	0.141	12.903	<0.001

Table 1) Change in HbA1c (%) when switching from NPH insulin to insulin glargine in relation to baseline BMI, gender and HbA1c

Baseline HbA1c	Patients changing to insulin glargine				Control group
	Women		Men		
	BMI 25 kg/m ²	BMI 30 kg/m ²	BMI 25 kg/m ²	BMI 30 kg/m ²	
HbA1c 5%	0.765	0.834	0.554	0.623	0.625
HbA1c 6%	0.444	0.512	0.232	0.301	0.358
HbA1c 7%	0.121	0.19	-0.092	-0.022	0.1
HbA1c 8%	-0.204	-0.134	-0.42	-0.349	-0.157
HbA1c 9%	-0.535	-0.463	-0.76	-0.686	-0.42
HbA1c 10%	-0.881	-0.805	-1.125	-1.044	-0.699
HbA1c 11%	-1.261	-1.176	-1.542	-1.447	
HbA1c 12%	-1.704	-1.602	-2.047	-1.93	
HbA1c 13%	-2.249	-2.122	-2.684	-2.535	
HbA1c 14%	-2.939	-2.778	-3.487	-3.3	

Figure 1) Scatterplot of 1,859 patients showing incremental costs and incremental benefits of IG versus NPH when applying an overall mean treatment effect (MTE). The incremental cost-effectiveness ratio was estimated at £28,925.

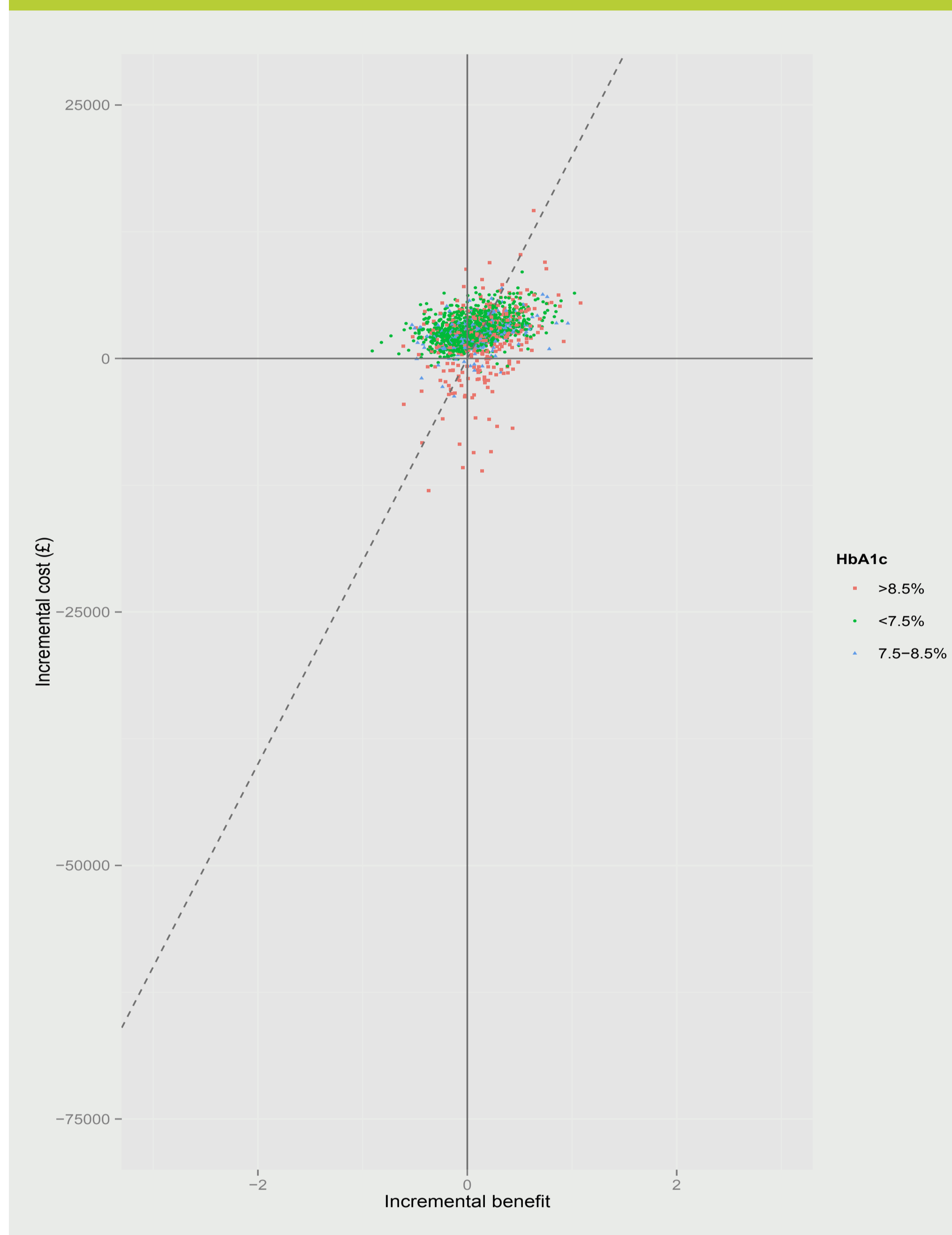
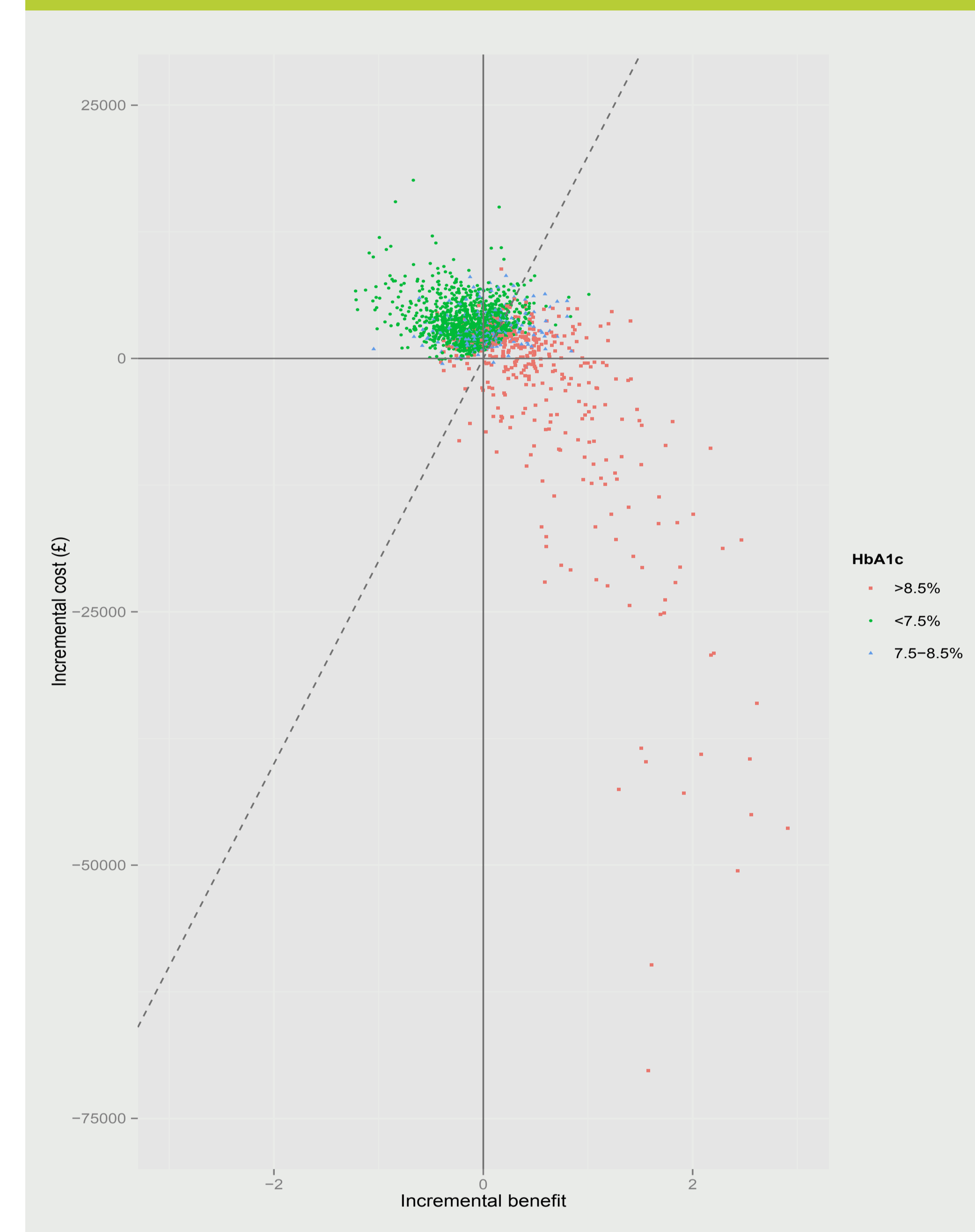


Figure 2) Scatterplot of 1,859 patients showing incremental costs and incremental benefits of IG versus NPH when applying baseline HbA1c, BMI and sex adjusted treatment effects (ATE). The incremental cost-effectiveness ratio was estimated at £57,279.



Conclusion

Within an environment of extreme financial budgetary constraints healthcare systems are increasingly looking to minimize drug budget expenditure. Applying an average treatment effect to an average cohort has the potential to distort the predicted costs and health benefits.

The identification of patient characteristics associated with greater potential for health gain and reduced cost is an important goal, particularly for payers.

The analysis of PLD alongside simulation model output provides an additional mechanism for informing healthcare decision-making.

References

- [1] Palmer AJ, Roze S, Valentine WJ, Minshall ME, Foos V, Lurati FM, Lamert M, Spinass GA. The CORE Diabetes Model: Projecting long-term clinical outcomes, costs and cost-effectiveness of interventions in diabetes mellitus (types 1 and 2) to support clinical and reimbursement decision-making. *Curr Med Res Opin* 2004; 20(S1):S5-S26.
- [2] Osterbrand M, Fahlén M, Odén A, Eliasson B. A method to predict the metabolic effects of changes in insulin treatment in subgroups of a large population based patient cohort. *Eur J Epidemiol*. 2007;22(3):151-7.

Table 3) Increment costs, benefits and cost-effectiveness applying mean and baseline HbA1c adjusted treatment effects

	Baseline HbA1c (%)		
	<7.5%	7.5-8.5%	>8.5%
Total number	1,178	285	396
Mean treatment effect			
Incremental cost	£2,698	£2,331	£1,885
Incremental benefit	0.07	0.09	0.14
ICER	£40,749	£26,008	£13,543
Adjusted treatment effect			
Incremental cost	£3,501	£2,755	-£3,182
Incremental benefit	-0.13	0.03	0.53
ICER	-£26,565	£80,445	-£6,024