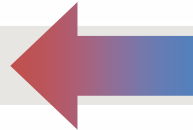


Cost-utility of Insulin Aspart compared with Recombinant Human Insulin in treatment of type 1 diabetes mellitus in Poland

Robert Plisko, Daria Szmurlo, Przemyslaw Rys, Anna Gurda
Jakub Rutkowski, Iwona Skrzekowska, Magdalena Wladysiuk
HTA Consulting Poland

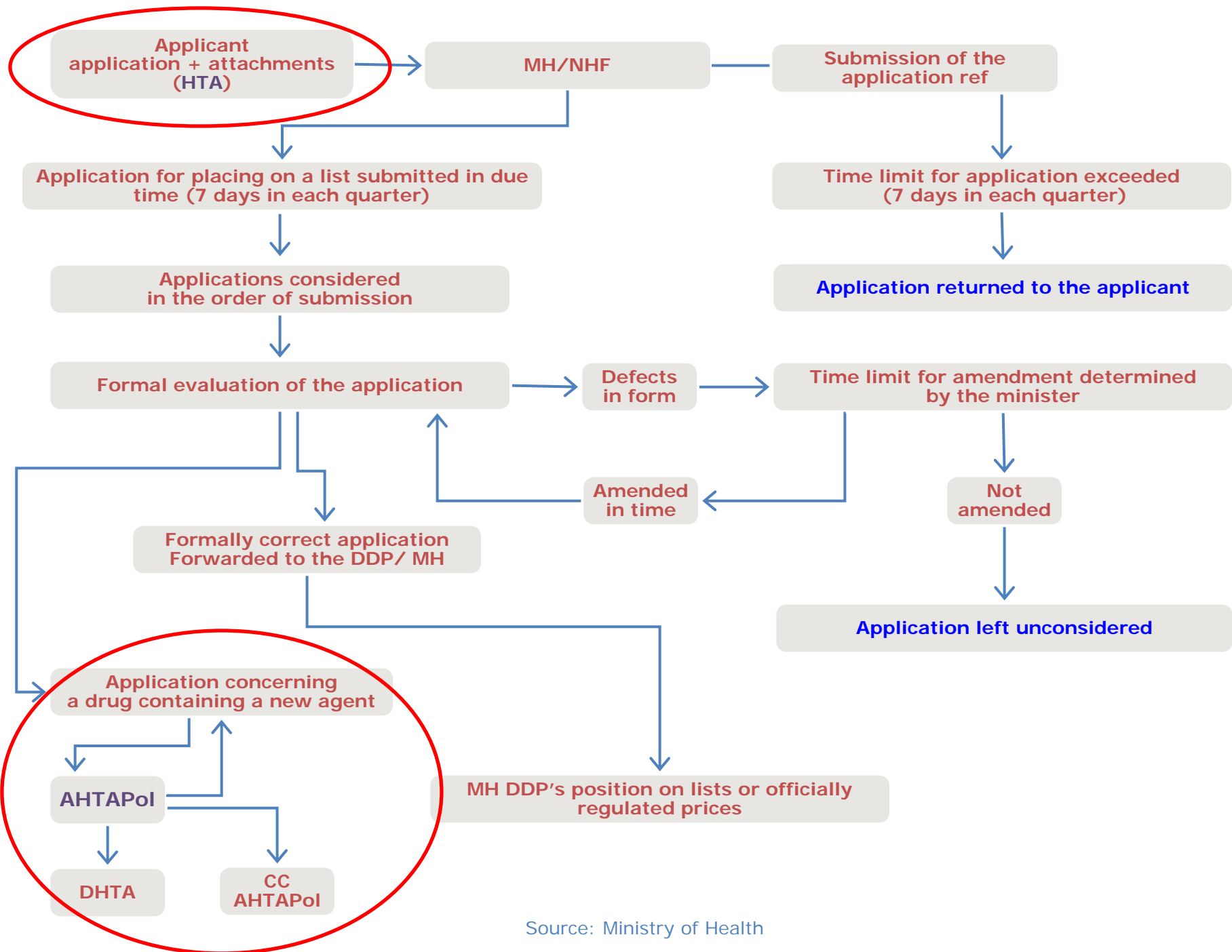
Analysis Sponsor: NovoNordisk Poland

Overview

- 1 HTA and reimbursement in Poland 
- 2 Efficacy and safety of insulin aspart
- 3 Relationship between surrogates and clinical outcomes
- 4 Cost utility of insulin aspart in Poland

Use of Health Technology Assessment

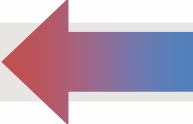
- required by law and submitted to the Agency for Health Technology Assessment in Poland (**AHTAPoI**)
- appraise by the independent **Consultative Council** as a base for recommendations concerning financing of health care services from public means



Analyses required during reimbursement process in Poland

- efficacy and safety (clinical analysis)
- cost-effectiveness (utility)
- the effect on reimbursement costs (*budget impact*)
 - for a specific medication, if the active agent has not been listed
 - for a specific medication and its alternative brand, if the active agent has been listed

Overview

- 1 HTA and reimbursement in Poland
- 2 Efficacy and safety of insulin aspart 
- 3 Relationship between surrogates and clinical outcomes
- 4 Cost utility of insulin aspart in Poland

Efficacy and safety of insulin aspart vs regular human insulin

Results of systematic review

Target population

Inclusion criteria:

- patients with type 1 diabetes mellitus regardless of age (adults and children)

Exclusion criteria:

- studies including only pregnant women or those with gestational diabetes mellitus
- studies with different antihyperglycaemic co-therapy in treatment arms
- studies, in which less than 10 patients were enrolled

Results

Statistically significant difference in favor of insulin aspart with respect to:

- the increased **treatment satisfaction**
- the reduction of **HbA1c level**
- the reduction of **PPG level after breakfast**
- the reduction of **PPG level after lunch**
- the reduction of **PPG level after dinner**
- the reduction of the risk of **nocturnal hypoglycemia**

Benchmarking of Systematic Reviews

	Efficacy					Safety		
	HbA1c	PPG	FPG	QoL	Treatment satisfaction	All Hipo	Nocturnal Hypo.	Severe Hypo.
HTAC 2007	+	+	nd	+	+	+*/ nd**	+*/ nd**	+
CADTH 2007	+	+	X	X	+	nd	nd	+
Cochrane 2006	+	X	X	X	X	nd	X	X

+ - superiority

nd - no differences

X - not analysed/no information/no conclusions

* - No of episodes

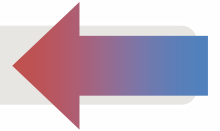
** - No of patients with ≥ 1 episode

Limitations

- Conclusions based on the results of clinical trials evaluating surrogates
- Surrogates do not describe direct benefit to the patient
- Its usefulness in evaluating such benefit depends on how much it allows for prediction of treatment effect on patient-important outcomes

Overview

- 1 HTA and reimbursement in Poland
- 2 Efficacy and safety of insulin aspart
- 3 Relationship between surrogates and clinical outcomes
- 4 Cost utility of insulin aspart in Poland



Objective

The aim of this analysis was to assess the association between

HbA1c and PPG

and

microvascular/macrovascular complications

in patients with type 1 diabetes mellitus

Interventions

- dietary treatment or modification of lifestyle
- oral antidiabetic drugs
- insulinotherapy

Results of the analysis HbA1c

increase in HbA1c level

- increase the risk of **retinopathy**
- RCT, observational and cross-sectional studies

increase in HbA1c level

- increase the risk of **visual deterioration** and **macular oedema**
- RCT

increase in HbA1c level

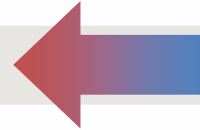
- increase the risk of **nefropathy**
- observational studies

increase in PPG

- increase the risk of **retinopathy**

Overview

- 1 HTA and reimbursement in Poland
- 2 Efficacy and safety of insulin aspart
- 3 Relationship between surrogates and clinical outcomes
- 4 Cost utility of insulin aspart in Poland



Insulin aspart - basal-bolus therapy

- Population: Diabetes mellitus type 1
- Intervention: Insulin aspart
- Comparator: Regular Human Insulin
- Time horizon: 50 years or until death
- Perspective: Public payer (NHF & patient)

The CORE Diabetes Model adapted to Polish settings

Bootstrap simulations

Results of cost-utility analysis

Cost of treatment		
	Insulin aspart	Human insulin
Insulins	17 515 PLN	13 244 PLN
Hypoglycaemic episodes	1 354 PLN	1 789 PLN
Others	34 585 PLN	35 015 PLN
Sum	53 454 PLN	50 048 PLN
Incremental cost	3 406 PLN	

1 Euro = 4.50 PLN (June 9th, 2009)

Results of cost-utility analysis

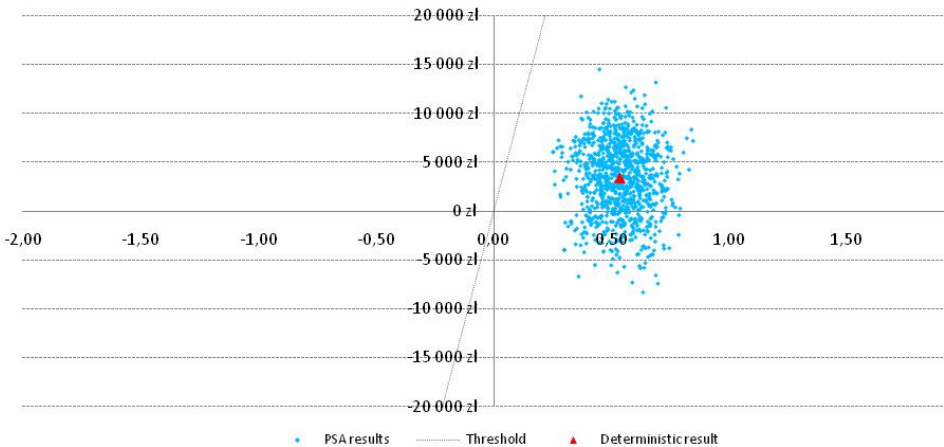
Effectiveness, ICER		
	QALY	LY
Insulin aspart	5.39	11.39
Human insulin	4.85	11.35
Incremental effect	0.54	0.03
ICER	6 351 PLN	99 259 PLN

1 Euro = 4.50 PLN (June 9th, 2009)

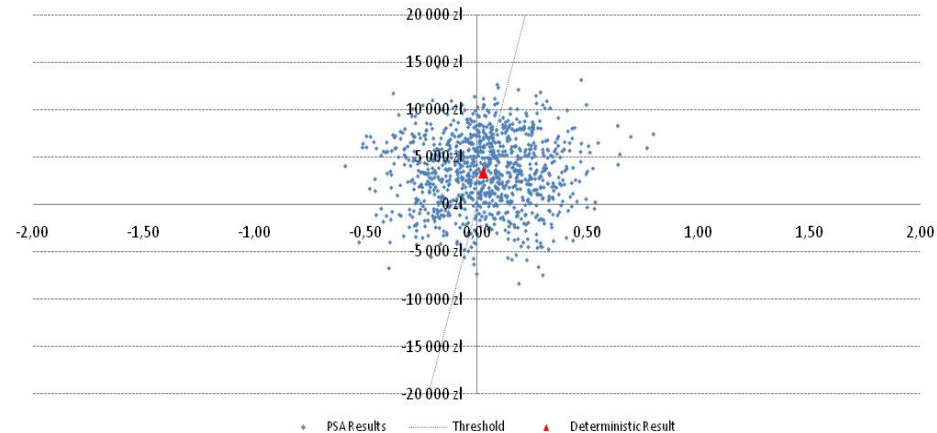
Probability sensitivity analysis

Probability of cost-effectiveness in Polish setting=100%
 (Threshold around 91 000 PLN)

Incremental cost per **QALY**

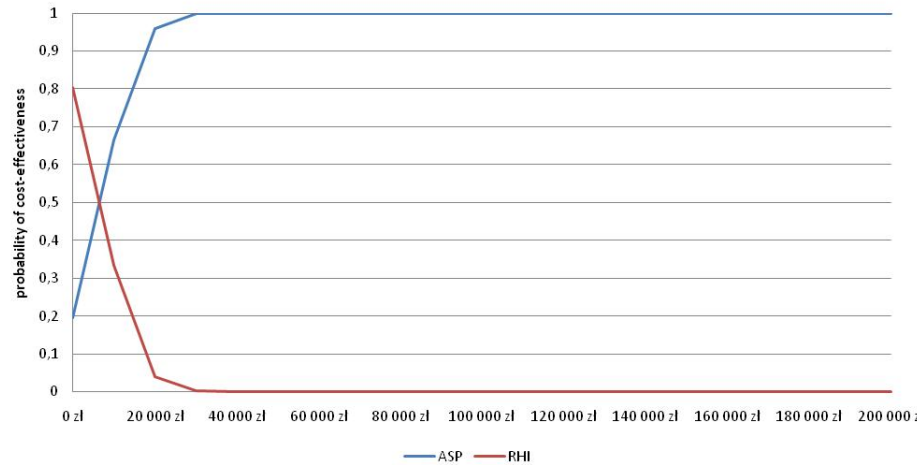


Incremental cost per **LYG**

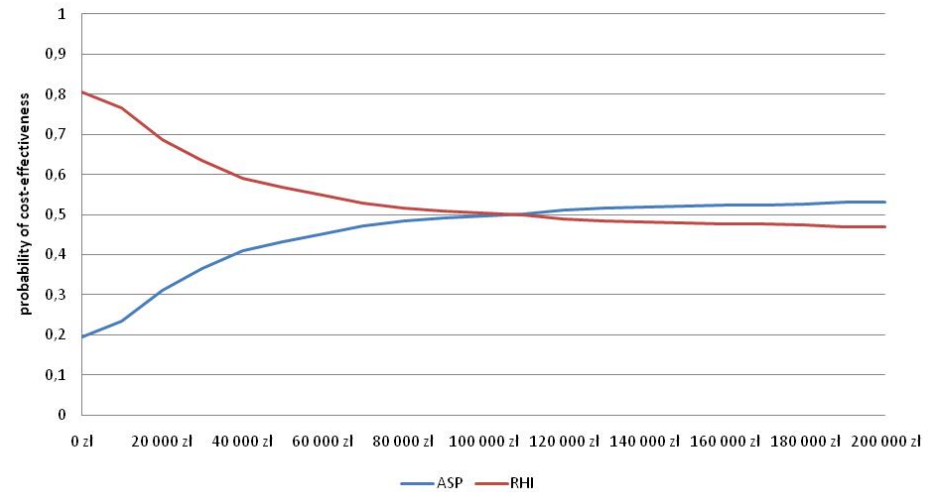


Cost Effectiveness Acceptability Curve

Incremental Cost per **QALY** Gained
Cost-Effectiveness Acceptability Curve (CEAC)



Incremental Cost per **LYG** Gained
Cost-Effectiveness Acceptability Curve (CEAC)



CUA summary

- ↓ number of **hypoglycaemic episodes** per patient
- ↑ **quality of life** of patients with diabetes mellitus
- NOT ↑ life expectancy

Insulin aspart (biphasic insulin aspart) is
cost-effective in Polish setting