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Review of ISPOR 13th Annual European Congress 2010



Costello Medical Consulting Ltd. attended the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 13th European Congress in Prague, Czech Republic, on 6th-9th November 2010.

The meeting was titled “Health Technology Assessment: A European Collaboration” and our delegates were allocated across a range of different sessions in order to get a full overview of the congress and to identify the main themes, which are presented below.

Themes at ISPOR European Congress 2010

Harmonising the European HTA Process

- A central theme in the congress was the need to harmonise the methodologies of the 30 European governmental HTA agencies, such that their findings can be compared easily across the EU.

Areas of harmonisation may include:

- Evidence requirements from manufacturers
- Methods of reviewing the data and economic models used during the HTA process
- The clinical outcomes considered, including the use of surrogate end points, as well as the patient reported outcomes which should be taken into account.
- The perspectives considered by agencies (just the healthcare system or a wider societal perspective?)
- Current efforts are focused on improving communication between individual HTA agencies and establishing an EU network of these (EUnetHTA: <http://www.eunetha.net>), both of which would be particularly valuable for countries lacking strong HTA agencies.

Promoting Innovation

- A recurring theme at the congress was the need to encourage the development of, and increase access to, innovative products, at a time when health budgets throughout Europe are under considerable pressure.

- This may require a reorganisation of the priorities of payers and HTA agencies across the region to recognise and promote ‘innovative’ products (broadly defined as those which represent a significant advancement in treating a specific disease).
- Value-based pricing (see below) may also play a major part in promoting innovative medicines.

Value-Based Pricing

- In many European countries, value-based pricing has been proposed as a solution to the problem of how to provide access to innovative medicines whilst simultaneously controlling healthcare expenditure.
 - Under such systems, payers would decide on pricing and reimbursement of medical products based on the perceived value of these products.
 - Such value would incorporate a measure of the innovation of a product, the clinical need in a specific disease area, societal views and other factors; but value is likely to differ significantly from one country to the next.
 - It was widely acknowledged that estimating a product's value at launch is difficult and that value may have to be demonstrated over the longer term and in real-life practice.
 - Managed entry schemes allow innovative products to enter the market before their true value in clinical practice has necessarily been fully demonstrated. Although these schemes offer a method of relating price directly to the value seen in the clinic, they may not fully address the societal value of products.

Real World Data

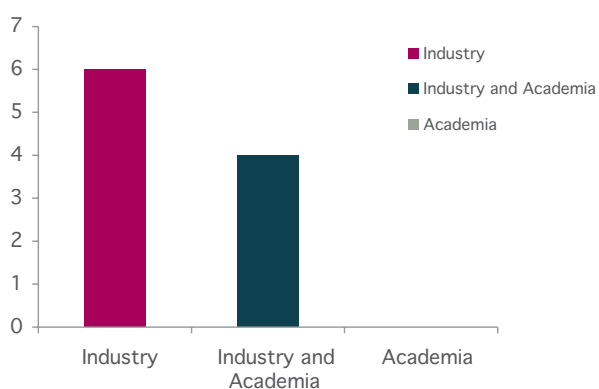
- Real world data, in addition to that available from controlled clinical trials, was highlighted as being increasingly critical in the appraisal of therapeutic products by payers and HTA agencies.
- Such data enables better informed decisions about reimbursement and allows for the comparison of a product with currently available treatments in a setting that more closely reflects real life.
- Therefore, in addition to demonstrating absolute clinical efficacy, manufacturers should be prepared to demonstrate the relative effectiveness of their products, typically through observational studies and, where relevant, registry data. This can aid payers in determining the true value of a product at its launch.
- A point for consideration is the suitability of European-wide relative effectiveness data compared to the need to collect this evidence on a country by country basis to most accurately reflect the context in individual healthcare systems.

In addition to identifying these broad themes during the congress, our delegates undertook a more detailed study of the data display in selected therapeutic areas. In the remainder of this report, you will find their analysis of the material that was presented on pulmonary hypertension, haematological malignancies, pancreatic cancer, ophthalmology and type 2 diabetes.

Pulmonary Hypertension

We identified 10 posters on the subject of pulmonary hypertension. Of these studies, 6 were solely sponsored and conducted by Pfizer and 4 studies were collaborations between industry and academia (Figure 1). The majority of studies related to pulmonary arterial hypertension (PAH) with only 1 study on chronic thromboembolic pulmonary hypertension (CTEPH) and 1 study relating to idiopathic and familial pulmonary hypertension.

Figure 1: Funding sources for publications on pulmonary hypertension



Clinical Trial Data

Of the poster presentations sponsored by Pfizer, 5 reported data from randomised clinical trials.

- Two posters by the same author considered quality of life in PAH patients, using data from the Galie 2005 trial that compared sildenafil to placebo in adult patients with PAH.¹ The first poster compared PAH patients to the healthy population and found that adults with PAH had significantly poorer SF-36 scores compared to control patients. Furthermore, SF-36 scores were considerably worse in patients with a WHO functional class III or IV.² Data from the same trial was also used to estimate health-state utilities in PAH;³ values derived from the SF-36 questionnaire tended to be higher than those derived using the EQ-5D, and patients self-rated their health state significantly lower than estimates derived from questionnaire response. The authors conclude that the method used to estimate HRQoL may have substantial implications in further analyses.
- Analysis of data from an RCT comparing sildenafil to placebo in children aged 1-17 demonstrated that sildenafil treatment significantly improved pVO_2 , mean pulmonary arterial pressure, pulmonary vessel resistance index and cardiac index.⁴ However there did not appear to be any difference between HRQoL scores between the two groups. Further clinical outcomes from this trial were also presented in a separate poster, with improvements in VO_2 shown to be associated with improvements in clinical end points, including WHO functional class and physician global assessment of change.⁵
- Similar results were demonstrated by data from a clinical trial comparing sitaxentan to placebo in adults.⁶ Clinical outcomes significantly improved with sitaxentan but SF-36 physical functioning scores were not affected.

Economic Evaluation

Cost and budget impact analyses were the subject of 3 posters relating to pulmonary hypertension; all were conducted in hospitals or academic institutions and commercially sponsored.

- An economic analysis sponsored by Bayer (Spain) assessed the cost-effectiveness of three PAH treatments, iloprost (inhaled), epoprostenol (intravenous) and treprostiniil (subcutaneous), using a Markov model from the perspective of the National Health Service in Spain.⁷ Results showed iloprost to be dominant at a three-year time horizon.
- Another study sponsored by Bayer (USA) looked at the direct medical costs of managing CTEPH.⁸ The total health care costs for patients with CTEPH were almost 6 times higher than those of controls without CTEPH, with inpatient costs

being the largest contributor. New treatments that result in reductions to inpatient stays and outpatient visits could therefore offer significant economic benefits.

- A budget analysis model sponsored by GSK (Poland) concluded that introducing ambrisentan as a treatment for pulmonary hypertension would lead to savings from a public payer's perspective.⁹

A final study sponsored by Pfizer examined the patterns of care and health utilization costs in PAH using data from the MarketScan Commercial Claims and Encounters Database, USA.¹⁰ Patients who had at least one pharmacy claim for sildenafil (Revatio®) were identified and analysed for health utilization costs. In the subsequent 6-month period following initiation of sildenafil it was found that overall healthcare utilization remained unchanged but the total healthcare costs increased due to increased costs of PAH pharmacotherapy.

Haematological Malignancies

We identified 17 poster presentations and 2 podium presentations on the subject of haematological malignancies. The majority were funded by industry, often in collaboration with academic institutions, with 4 presentations being purely academic studies (Figure 2). There was 1 poster and 1 podium presentation specifically relating to acute myeloid leukaemia (Figure 3).

Figure 2: Funding sources for publications on haematological malignancies

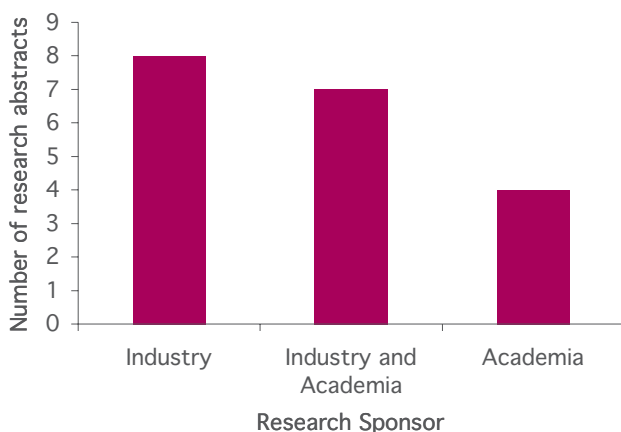
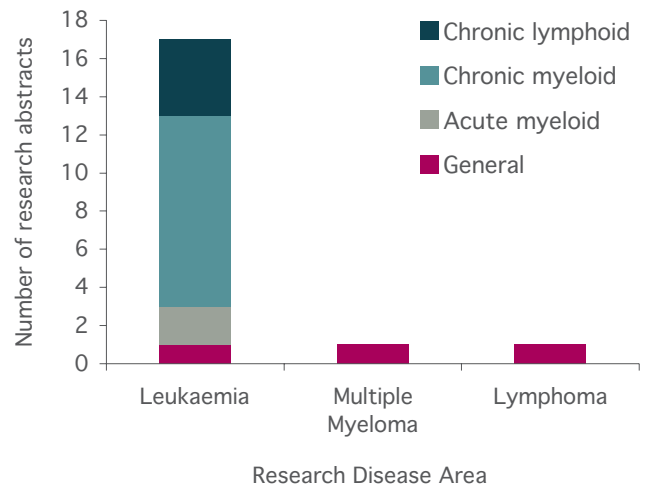


Figure 3: Number of studies by disease area



Acute Myeloid Leukaemia

The only presentation relating directly to AML was a podium presentation which discussed the development of a new decision model for describing the full course of the disease.¹¹ The rationale for developing a new decision model was due to a new diagnostic test that identifies molecular subtypes in AML, and the need to evaluate the cost-effectiveness of this test. Using a simulated representative patient cohort, time-to-event and survival time estimates were calculated. The internal and external validity of the model were then assessed; the overall survival estimated using the model was found to correspond to real-life data. The authors noted that improvements could be made within the model, including discussions with clinical experts and the use of a larger data set. Overall the model was demonstrated to give a good representation of patient characteristics and showed a good-fit up to 3 years, and was therefore proposed to be useful in assessing the cost-effectiveness of interventions in AML.

Economic Analyses

There were 10 economic analyses relating to haematological disorders presented at ISPOR, including 6 cost-effectiveness studies, 1 cost-utility study, 2 cost studies using real world data and a systematic review.

In relation to chronic myeloid leukaemia (CML), 5 of 6 economic studies assessed the cost of second line treatments compared to standard care or high dose imatinib in patients with imatinib-resistant CML.

- Two groups from BMS reported the dominance of dasatinib in cost-effectiveness¹² and cost utility¹³ analyses vs. high dose imatinib in imatinib-refractory CML. A retrospective study in Mexico, also funded by BMS, demonstrated that cost of care for imatinib-resistant CML increases due to additional demand for medical resources.¹⁴

- The cost-effectiveness of omacetaxine vs. standard care in imatinib-resistant CML was demonstrated in a Markov model from the French healthcare perspective.¹⁵ The authors found that omacetaxine was cost-effective at a threshold of €30,000 in patients resistant to tyrosine kinase therapy.

Two studies supported by Roche demonstrated the dominant cost effectiveness of rituximab in chronic lymphoid leukaemia (CLL)¹⁶ and Non-Hodgkin's Lymphoma¹⁷ in combination with chemotherapy compared to chemotherapy alone, based on Markov models from the Brazilian and Portuguese healthcare systems respectively.

Two poster presentations analysed several decision models evaluating treatment strategies in CML by a systematic overview¹⁸ and a direct critique¹⁹. Both studies concluded that there was substantial variation in the modelling approaches and suggested that models should be validated against independent long-term data.

Utility Values

GSK²⁰ and Novartis²¹ sponsored posters which considered utility values in CLL and CML, respectively, among the UK general public. Both studies used time trade-off methodology to calculate mean utility values according to increasing severity of disease state and treatment response preferences; the GSK study also assessed visual analogue scores for the same disease states.

- In CLL there was a significant preference for progression free treatment, as would be expected, which corresponded to a higher health related quality of life (HRQoL) score. Interestingly, patients suffering from adverse events were deemed to have a lower HRQoL than the anchor disease state prior to treatment, even if they had progression free survival response. Thus, the safety profile of an ideal drug should be considered as important as the efficacy profile.
- In CML, health states with a molecular response to treatment were associated with a higher preference than a haematologic response; the impact of different treatment response appears to have a direct effect on HRQoL and can be used in determining QALYs.

Antifungal Treatment in Haematological Malignancies

One poster presentation and a podium presentation addressed the use of antifungal treatments in patients who had received chemotherapy for haematological malignancies, particularly whether antifungal prophylaxis was effective in reducing the incidence and associated costs of invasive fungal infection (IFI). A retrospective single centre study assessed the occurrence of IFI, modes of treatment and the total

costs per episode in patients who had chemotherapy for AML.²² The study concluded that a change in management of IFI over the period of 2004-2006 was accompanied by a reduction in overall costs, namely due to a decrease in the use of antimycotics and shorter hospital stays.

Pancreatic Cancer

There were 2 poster presentations relating to pancreatic cancer, both funded by industry.

- A systematic review and meta-analysis was performed, funded by MedInsight Evidências, of all RCTs comparing adjuvant gemcitabine chemotherapy with observation only in patients with resected pancreatic cancer.²³ 15 trials were initially identified and 2 trials included in the final analysis. The combined hazard ratio was calculated as 0.59 (95% CI 0.50-0.70) for progression free survival and 0.81 (95% CI 0.67-0.98) for overall survival, with the authors concluding that adjuvant chemotherapy with gemcitabine improved survival compared to observation alone.
- A second study by Amgen assessed the resource use and costs among 4938 patients with metastatic pancreatic cancer.²⁴ Of those patients receiving chemotherapy, 76.4% received gemcitabine with an average of 9.5 doses over 109 days. The second most common therapy was the targeted agent erlotinib (20.1% of total patients) with 63.6% of patients receiving it in combination with gemcitabine. The mean cost per month of treating these patients was \$16,192, with the highest costs attributed to inpatient stays and outpatient visits; outpatient cancer therapy contributed only 5.3% of total monthly costs.

Overview of the Data Display

Thirteen posters were identified as relating to ophthalmology. The vast majority were commercially sponsored (11 of 13), with 8 of these being from one company, Alcon (Figure 4). This strong presence at ISPOR indicates that Alcon, the majority of which is owned by Novartis, are looking to present themselves as the leading pioneers of research in the area of eye disease.²⁵

Figure 4: Funding sources for studies on ophthalmology

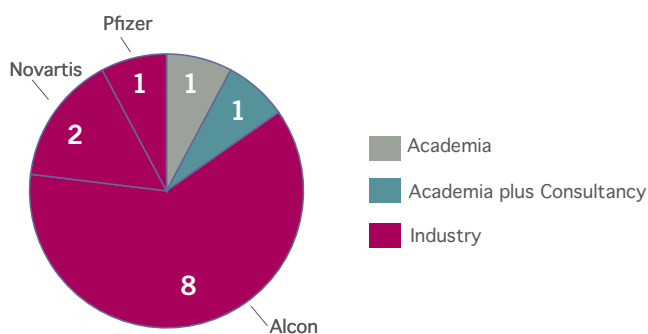
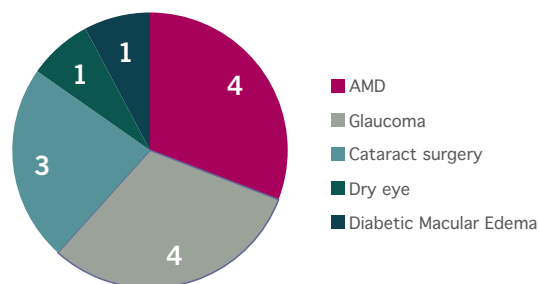


Figure 5: Number of studies by disease area



Economic Evaluations in Ophthalmology

Cost Comparison Studies

- The University of Barcelona performed a micro-costing analysis of direct healthcare costs for wet-AMD in Spain.²⁶ They acquired epidemiological data from the published literature and collected patient-level primary data on resource use from various hospitals in Spain. Although Avastin® is not yet an approved therapy for this indication in Europe, it was included in the analysis as off-label use in Spain is thought to be prominent. They found that treatment with Lucentis® had the highest medical costs per patient (€8,659 - €14,373) in comparison to Visudyne® plus photodynamic therapy (€5,812), Macugen® (€7,296) and Avastin (€3,112). The difference in purchase price of the drugs seemed to be

driving the difference in overall medical costs between treatments. For example, it was reported that Lucentis would cost €952 per administration compared to €14 for Avastin. The impact of an aging population on future costs of wet-AMD was discussed.

- Three posters from Alcon investigated the costs of glaucoma treatment in Sweden, the UK and Germany.^{27,28,29} Medication and interventional procedures were found to be the primary cost drivers of the disease, making up 94% of costs in Sweden, for example.²⁷ Annual costs per patient were found to be relatively low (€382 in Sweden, €345 in the UK and ranging from €226 to €809 in Germany depending on the severity of the disease).

Cost-Effectiveness Models

- All three cost-effectiveness studies in ophthalmology presented at ISPOR related to AMD. The two posters with links to Novartis demonstrated the cost-effectiveness of Lucentis versus the following comparators: best supportive care, Visudyne with photodynamic therapy and pegaptanib.^{30,31} Furthermore, the model produced in collaboration with IMS Health showed that Lucentis dosed as needed is more cost-effective or is a dominant option over the comparators and over other dosing regimens of Lucentis.³¹
- An academic group from the Netherlands developed a cost-effectiveness model that evaluated Avastin use in AMD.³² They found that the 8 week dosing schedule of Avastin was superior to the 4 or 6 week dosing regimens. Avastin cost-effectiveness was not compared to competitors such as Lucentis, but in light of the fact that it has been found to be significantly cheaper per patient (see University of Barcelona poster description above²⁶), it could pose a considerable market access barrier to Lucentis if it were to receive regulatory approval for this indication.

Quality of Life (QoL) Relating to Vision Impairment

QoL is Impaired as Vision Worsens (Case of Glaucoma)

- Disease progression in primary open-angle glaucoma is associated with worsening vision. One study from Alcon showed that progression is also associated with increasing impairment of QoL, as measured by the Health Utility Index (HUI3) and NEI-VFQ-25 tools.³³ The HUI3 score for early, moderate and advanced glaucoma differed from a normal population on average by 0.01 ± 0.09 , -0.06 ± 0.24 and -0.19 ± 0.28 , respectively. The conclusion was that a robust estimation of QoL must take into account the remaining field of vision in the best eye or in both eyes.

Type 2 Diabetes

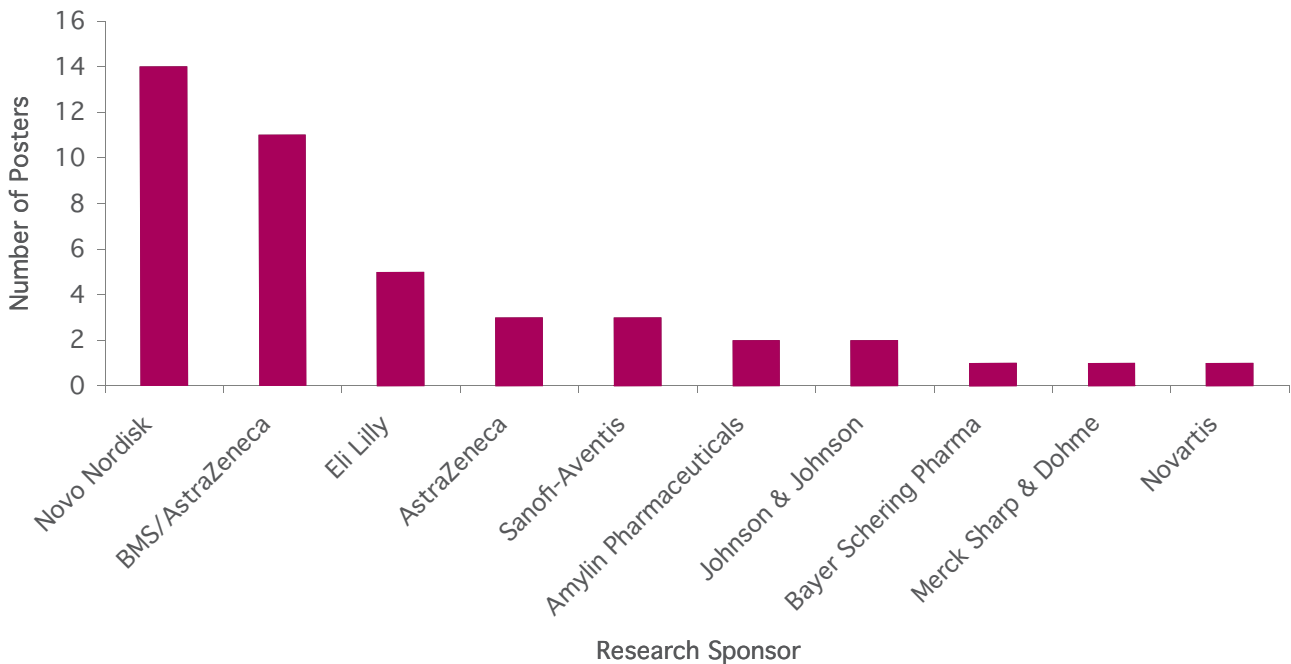
Measurement Methods

- A literature review sponsored by Alcon investigated the available vision-related QoL tools that have been used to measure the impact of cataract surgery.³⁴ It was concluded that the NEI-RQL-42 should be considered as the best tool in this case as it showed a robust development methodology and possessed good psychometric properties.
- Another poster from Alcon verified that a new tool for measuring disease-specific QoL in patients with dry eye, IDEEL (Impact of Dry Eye on Everyday Life) is as sensitive to change as previous time trade-off methods.³⁵
- A poster from Pfizer reported on a call centre method for collection of QoL data in a population of patients with diabetic macular oedema.³⁶ They claim it is a viable and efficient method of data collection in these patients, as the quality of data collected in this manner did not differ from that collected from face-to-face interviews. The method could be applied to a wide range of QoL studies.

We identified 53 posters on the subject of Type 2 Diabetes (T2D). The majority of these posters (27) presented economic data, whilst 17 posters presented health outcomes data, 5 posters specifically focused on Health-Related Quality of Life and 4 posters discussed more general issues in T2D.

Eleven posters were funded by academic institutions, with 42 posters funded by the pharmaceutical industry. The breakdown in poster funding by pharmaceutical company is presented in Figure 6 below. Novo Nordisk was the single biggest sponsor of T2D posters at the Congress, followed by the Bristol-Myers Squibb – AstraZeneca Diabetes Collaboration. This high level of industry sponsorship suggests a great deal of interest from the pharmaceutical companies working in this disease area and reflects the growing burden and continued unmet clinical need of T2D.

Figure 6: Poster funding sources stratified by sponsoring pharmaceutical company.



Economic Studies

The economic posters presented at the congress can be split into three broad categories:

- Cost-effectiveness/cost-comparison studies of T2D treatments
- Studies on the economic burden of T2D on healthcare systems
- Studies investigating different methodologies for conducting economic evaluations in T2D.

Please note that not all of the posters identified at the congress are reported here, as some were considered less relevant to this discussion.

Cost-effectiveness/ Cost-comparison Studies of T2D Treatments

Of the 15 studies included in this group, seven were funded by Novo Nordisk and focused on the cost-effectiveness of their new T2D drug, liraglutide. This suggests that Novo Nordisk's current strategy is to support a large number of studies that demonstrate the economic benefit of liraglutide compared to its main competitors across different countries in Europe, in order to enhance market access of their product.

All the cost-effectiveness studies utilised the CORE Diabetes Model to project long-term health outcomes and economic consequences of the interventions; efficacy data were taken from the LEAD liraglutide clinical trials. Further details on these studies are provided in Table 1 below.

Table 1: Summary of the key messages from the Novo Nordisk posters investigating the cost-effectiveness of liraglutide.

Poster Number	Country	Interventions	Main Conclusion
PDB38 ³⁷	Germany	Liraglutide vs. sitagliptin	Liraglutide cost-effective
PDB41 ³⁸	Slovak Republic	Liraglutide vs. rosiglitazone or exenatide	Liraglutide cost-effective
PDB42 ³⁹	Germany	Liraglutide vs. exenatide	Liraglutide cost-effective
PDB43 ⁴⁰	Poland	Liraglutide vs. sulphonylurea	Liraglutide cost-effective
PDB52 ⁴¹	Czech Republic	Liraglutide vs. rosiglitazone	Liraglutide cost-effective
PDB61 ⁴²	Bulgaria	Liraglutide vs. rosiglitazone or exenatide	Liraglutide cost-effective
PDB63 ⁴³	Romania	Liraglutide vs. rosiglitazone or exenatide	Liraglutide cost-effective

It is interesting to note the heavy focus of the Novo Nordisk posters on Eastern European countries, perhaps suggesting that they intend to launch liraglutide in these countries in the very near future and are therefore laying the economic framework to support applications for reimbursement.

Aside from Novo Nordisk, four of the posters in this group were sponsored by the BMS-AstraZeneca Collaboration (PDB 19,⁴⁴ 37,⁴⁵ 44⁴⁶ and 62⁴⁷). All four focused on the economic value of saxagliptin therapy, in Germany, Poland, Brazil and Mexico. The posters concluded that saxagliptin was a cost-effective or cost-acceptable treatment option in all four countries.

Sanofi-Aventis sponsored two posters (PDB 21⁴⁸ and 54⁴⁹), which compared the costs between insulin

glargine and insulin detemir in Germany and Spain. Both concluded that the use of insulin glargine results in substantial cost savings compared to the use of insulin detemir in these markets.

Eli Lilly & Co. sponsored two posters, which focused on their T2D drug exenatide. PDB36 examined the long-term cost-consequence of exenatide versus sitagliptin or pioglitazone in the USA and concluded that exenatide is associated with improved health outcomes and reduced costs associated with T2D complications, compared with the other two treatments.⁵⁰ PDB51 investigated the cost-effectiveness of exenatide versus insulin glargine or biphasic insulin aspart in Portugal; exenatide was demonstrated as being cost-effective compared to the other two treatments.⁵¹

Studies on the Economic Burden of T2D

Five posters looked more generally at the economic burden of T2D or T2D treatment practices on healthcare systems. The results from two of these are summarised below:

- PDB13 (funded by BMS-AZ) reported the preliminary results of a cohort study of the treatment costs of T2D in the Brazilian healthcare system. The two highest costs faced by patients were visits to a healthcare professional and T2D medication. Higher costs were also associated with older patients and patients with a long history of T2D.⁵²
- PDB22 (funded by Bayer Schering Pharma) assessed the economic impact of choosing one glucometer over another for self-monitoring of blood glucose by patients in Spain. They concluded that glucometers which do not require coding and have individually packed strips reduce the economic impact of self-monitoring by between 10% and 40%.⁵³

Methodology of Economic Studies in T2D

Two posters (PDB40⁵⁴ and PDB50⁵⁵) examined different methodologies of performing economic studies in T2D. The results from PDB50 are summarised below.

- PDB50 (sponsored by BMS-AZ) investigated the effect of including subsequent cardiovascular events into a T2D cost-effectiveness model. The investigators reported that inclusion of these events increased the face validity of the model, but had little impact on the cost-effectiveness. This suggests that models which do not include these factors are not significantly biased.

Health Outcomes Studies

Fifteen posters reported on studies of specific health outcomes in T2D. These posters can be split into those presenting: clinical efficacy/effectiveness data; safety and complications data; and treatment pathway data.

Clinical Efficacy/ Effectiveness Data

- PDB3 (academic) presented a meta-analysis of the efficacy and safety data for dipeptidyl peptidase-4 (DPP-4) inhibitors in T2D. The results suggest that DPP-4 inhibitors are moderately effective at improving glycaemia compared to placebo and have comparable efficacy to other hypoglycaemic agents. However, DPP-4 inhibitors demonstrate a more favourable safety profile than other hypoglycaemic agents.⁵⁶
- PDB9 (Eli Lilly) used the CORE Diabetes Model (CDM) to predict lifetime patient response to exenatide, compared with insulin glargine, in the UK setting. Over a 50-year time horizon it was predicted that patients treated with exenatide

would have improved life expectancy and quality of life, a delay in the time to onset of diabetes-related complications and a reduction in the cumulative incidence of these complications.⁵⁷

Safety and Complications Data

- PDB16 (Sanofi-Aventis) used an historic cohort study of German patients to conclude that patients receiving insulin glargine have a lower incidence of diabetic foot syndrome and macrovascular complications compared to patients receiving NPH insulin.⁵⁸
- PDB17 (Novo Nordisk) performed a systematic review and meta-analysis to investigate the relationship between HbA_{1c} and the appearance of macrovascular complications in T2D. The results indicate that HbA_{1c} levels may constitute a potential surrogate marker for macrovascular complications.⁵⁹
- PDB73 (BMS-AZ) performed a subgroup analysis of the PANORAMA study⁶⁰ and concluded that severe hypoglycaemia is a greater problem in patients treated with insulin than those treated with oral antidiabetes drugs.⁶¹

Treatment Pathway Data

- PDB79 (Sanofi-Aventis) studied the duration of first insulin therapy in patients with previously uncontrolled T2D, comparing insulins glargine, detemir and NPH. Patients who commenced treatment on glargine remained on their initial insulin treatment for longer than those who commenced with either detemir or NPH.⁶²
- PDB81 (Merck Sharp & Dohme) examined the time to add-on medication in T2D patients who have failed metformin monotherapy, in the USA. The study reported that the median time for such patients to receive additional antihyperglycaemic medication is 14 months. Evidently there is scope to improve the management of metformin-failure patients through decreasing the time between patients failing metformin therapy and receiving further pharmaceuticals.⁶³
- PDB8 (Eli Lilly & Co.) presented results from an ongoing prospective observational study (CHOICE) in Germany, which examined 6 month treatment outcomes in patients receiving either insulin or exenatide. As the two cohorts presented significant differences at baseline, direct comparisons of treatment outcomes could not be made. However, the authors concluded that the results for both insulin and exenatide are consistent with the results from phase III clinical trials, thereby demonstrating the value of these treatments in the real-world setting.⁶⁴
- PDB83 (Eli Lilly & Co.) examined the time to treatment modification, in patients receiving either exenatide or insulin glargine. Exenatide treated patients had a longer time until treatment modification than glargine patients. Exenatide patients were also less likely to

discontinue or intensify treatment, but more likely to switch their treatment than glargine-treated patients.⁶⁵

- PDB91 (BMS-AZ) examined the treatment patterns and achievement of therapeutic goals in a cohort of Brazilian T2D patients. The authors concluded that metformin and sulphonylurea are the most frequently used drugs and that the majority of patients do not meet national T2D therapeutic targets. This presents a possible market access opportunity, whereby a manufacturer of T2D medications could support doctors and patients through an intensive educational programme on the importance of meeting T2D treatment targets and strategies to improve achievement levels.⁶⁶
- PDB7 (Sanofi-Aventis) analysed the data from a longitudinal study to identify predictors for the initiation of basal supported oral therapy (BOT) in T2D patients. Apart from insufficient metabolic control, they identified patient age, type of OADs and quantity of OADs as predictors of patients who may need to begin BOT. This could prove useful to clinicians in identifying patients who require earlier initiation of BOT, thereby potentially avoiding unnecessary micro- and macro-vascular complications.⁶⁷
- PDB70⁶⁸ and 76⁶⁹ concluded that T2D patients reported worse QoL than people without T2D, particularly in the pain/discomfort and anxiety/depression health dimensions.
- PDB76 reported that a longer duration of diabetes, the presence of complications and the use of insulin were associated with negative impacts on the QoL.
- PDB68 suggested that experience of hypoglycaemic episodes, obesity, gender and perceived knowledge about T2D have a significant effect on patients' QoL.⁷⁰
- PDB75 specifically examined the impact of perceptions of weight on patients' health-related well-being.⁷¹ The results suggest that weight is a key concern of T2D patients and is associated with lower measures of HRQoL. Therapeutic options to help T2D patients reduce their weight may have a positive impact on patients' lives, as well as having obvious clinical benefits.

Health-Related Quality of Life (HRQoL) Studies

Four posters presented HRQoL of patients with T2D; AstraZeneca, the BMS-AZ Collaboration, Novo Nordisk and J&J provided funding for one poster each in this section.

- Three posters (PDB 68, 70 and 76) reported on the HRQoL of T2D patients in Sweden, China and Brazil respectively.

Further Assistance

Please do not hesitate to contact us if you would like any further information on the themes or research presented above. If you would like to receive a complimentary in-depth review of the data display from a future ISPOR congress in a therapeutic area of particular interest to you, please send us a request.

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- 3 Mychaskiw MA, Berger A, Mardekian J, Hwang L, Oster G. Methods for estimating health-state utilities in pulmonary arterial hypertension. *ISPOR 13th Annual European Congress 2010*; PCV108
- 4 Cappelleri JC, Hwang L, Mardekian J, Mychaskiw MA. Response profiles of sildenafil citrate on exercise capacity, hemodynamic function and health-related quality of life in children with pulmonary arterial hypertension. *ISPOR 13th Annual European Congress 2010*; PCV17
- 5 Cappelleri JC, Hwang L, Mardekian J, Mychaskiw MA. Measurement properties of peak VO₂ in children with pulmonary arterial hypertension. *ISPOR 13th Annual European Congress 2010*; PCV138
- 6 Hwang L, Lie X, Teal S, Louie M, Mychaskiw MA. The effect of sitaxentan on exercise capacity, hemodynamic function, and health related quality of life in adults with pulmonary arterial hypertension. *ISPOR 13th Annual European Congress 2010*; PCV16
- 7 Roman A, Barbera JA, Escribano P, Sala ML, Febrer L, Casado MA. Economic evaluation of iloprost, epoprostenol and treprostinil for the treatment of pulmonary arterial hypertension. *ISPOR 13th Annual European Congress 2010*; PRS33
- 8 Said Q, Martin BC, Joish VN, Gabriel P, Kreilick C, Seal B, Williamson T, Methai SC. Cost of managing chronic thromboembolic pulmonary hypertension to managed care. *ISPOR 13th Annual European Congress 2010*; PCV52
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- 10 Mychaskiw MA, Berger A, Mardekian J, Oster G. Patterns of therapy, healthcare utilization, and healthcare costs in patients with pulmonary arterial hypertension (PAH) initiating therapy with sildenafil: findings from retrospective analyses of administrative healthcare claims data. *ISPOR 13th Annual European Congress 2010*; PCV54
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