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# Review of ISPOR 14th Annual European Congress 2011



Costello Medical Consulting attended the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 14th Annual European Congress in Madrid, Spain from the 6th to 8th November 2011.

The meeting was entitled “Rational Health Care Decision Making in Challenging Economic Times”. A short summary of some of the most interesting and relevant themes from the congress is presented below.

### Themes of ISPOR 14th Annual European Congress 2011

#### Value Based Pricing

With value based pricing (VBP) now a reality in Germany and imminent in the UK, this was a central theme of the congress.

- The consensus among both health economists and payers was that VBP was a good idea in hard economic times, as it should result in a fair price being set for new drugs. However, there was less agreement on how VBP will work in reality and on what criteria the pricing will be based.
- The main question up for debate was how to measure and cost aspects of ‘value’ that fall outside of the current cost per QALY model in a fair, consistent and transparent manner.
  - One solution posed was to revive multi criteria decision analysis, which allocates different weightings to multiple quantitative outcomes of interest.
  - If a wider societal perspective is to be taken, the measurement and valuation of outcomes such as caregiver burden and productivity will have to develop rapidly.
- The transparency of VBP seems to be a key issue, especially as it was agreed that in order to allow scope for negotiation by manufacturers, it would not be possible to publish the actual value based price.
  - In the UK, it was largely agreed that the assessment of cost-effectiveness by NICE will likely remain transparent, but it was unclear whether subsequent discussions by the department of health would be similarly visible.
  - The issue that many health economists had with VBP was that it was unclear how much of the decision making will follow a quantitative structure, which could be fully transparent, and how much would be based only on unquantifiable debate.
  - The current experience in Germany is that transparency is difficult to achieve.

#### Real World Evidence

The utility of observational data has been a central theme at previous ISPOR congresses, and was discussed frequently again this year. The continued discussions on this topic could reflect either its importance for decision making or the lack of clarity on where observational data should be employed in the decision making process.

- The main value of real world evidence is that it is seen as the only way to confirm the findings of cost-effectiveness models that are based on data from randomised controlled trials.
- Both payers and manufacturers acknowledged the value of real world data and agreed that such data should start to be collected as early on in the drug development process as possible, in order to inform reimbursement decisions.
- The main point of friction between industry and decision makers, however, was that it is impossible to collect large-scale real world evidence if a drug is not reimbursed in the first place. Therefore observational data must not be a pre-requisite for reimbursement, but rather act as a supplementary source of information throughout the lifetime of the drug.

#### The Feasibility of a Centralised European Health Technology Assessment (HTA) Agency

Experts believe that a centralised European HTA agency is possible in theory, but only to a point and that such a development is unlikely to happen soon. The main benefit of such a centralised agency would be to reduce the duplication of effort on both the part of the HTA agencies and that of the manufacturers.

- The consensus was that the relative effectiveness of interventions is not likely to differ substantially across Europe. If differences are observed, then this is likely to be a reflection of differences in clinical practice rather than differences in clinical responses. Therefore a central body, perhaps an extension of the European Medicines Agency (EMA), could theoretically be responsible for evaluating relative effectiveness. The issue of

different interventions being used in different countries was not thought to be an issue, as a central comparison to all possible (licensed) products could be performed.

- It was not thought possible, however, for a centralised body to deal with the economic evaluation of interventions for the following reasons:
  - Countries across Europe differ in their opinions on what categories of costs should be included in economic assessments of health technologies.
  - Many aspects of healthcare resource use differ between geographical areas, such as length of hospitalisation and access to community healthcare services. The cost of delivering healthcare also differs depending on the cost of living – a factor that again varies by country.
  - Countries have different willingness to pay thresholds, reflective of the substantial difference that there is in Gross Domestic Product (GDP) per capita across Europe.
  - Differential price setting for drugs across European countries must be permitted and not made public knowledge, otherwise equitable access would be jeopardised or financial compensation from rich to poor countries would need to be exercised.

### Likely Future Themes

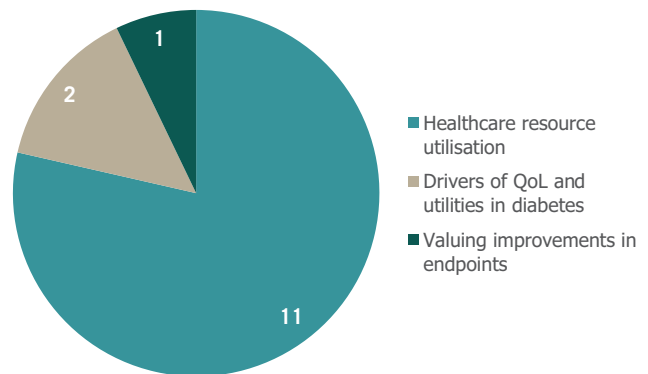
- Value based pricing will be introduced in the UK in 2014; therefore the practical implementation of this process is likely to remain a topic for discussion in the coming years.
- Although the development of a centralised European HTA agency is unlikely to occur in the near future, the improvement of HTA efficiency is expected to remain as a key theme of future ISPOR meetings, particularly with the ongoing healthcare reforms in Germany, the UK and the US.
- Criteria other than cost-effectiveness appear to be increasingly important in healthcare decision-making, for instance, risk-sharing agreements and bypasses such as the NICE end-of-life criteria and the newly instated Cancer Drugs Fund in the UK.
- The heterogeneity in cost-effectiveness of medical interventions between different populations, and the challenges of matching specific patient groups to appropriate treatments, will become ever more important with the identification of biomarkers and continued development of personalised medicine.

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 a selection of their analysis of the key cost and outcomes data that was presented at the meeting.

## Poster Research in Diabetes

A large number of posters were presented at the European ISPOR Congress 2011 in the disease area of diabetes. Fourteen abstracts were identified that specifically considered healthcare resource utilisation in diabetes, aspects of quality of life (QoL), utilities and valuing improvements in endpoints (see Figure 1 for topic breakdown). The objectives and top-line findings of these pieces of research are outlined below.

Figure 1: Breakdown of diabetes posters by research topic



### Healthcare Resource Utilisation

A retrospective analysis of patient-level data by Burslem et al (Boehringer Ingelheim) estimated the average annual cost of treating type 2 diabetes (T2D) patients with insulin in the UK.<sup>1</sup>

- The costs of insulin, test strips for self-monitoring of blood glucose levels (SMBG), and additional healthcare professional (HCP) time spent with patients initiated on insulin were evaluated.
- The annual weighted average costs of insulin and test strips were estimated to be £393 and £180 per patient, respectively, and a survey of 100 HCPs revealed that initiation with insulin leads to a total increase of 8 HCP-contacts per patient, which was calculated to generate additional costs of £103 per patient.<sup>1</sup>
- In conclusion, insulin initiation was found to increase the cost of care not only due to the costs of insulin, but also because of the package of resources that insulin therapy requires.<sup>1</sup>

Two posters discussed the costs of diabetes and its treatment, one in Poland and the other in Croatia.

- Leśniowska et al reported preliminary results from an analysis (sponsored by Novo Nordisk) that estimated the direct and indirect costs of diabetes mellitus and its complications in Poland from 2004 to 2009.<sup>2</sup>
  - During this time period, a continuous increase in the direct costs of diabetes was observed, and the costs of health services (mainly hospital and specialist care) for diabetes doubled. In 2009, the costs associated with the treatment of complications of diabetes (excluding expenditures for drug reimbursement) were over four times greater than the direct costs of diabetes itself.<sup>2</sup>
  - The majority of indirect costs incurred by both diabetes itself and diabetes-related complications (89%, for both) were derived from loss of productivity due to incapacity to work (ie. unemployment due to poor health). Only 11% of the indirect costs of diabetes were, therefore, related to loss of productivity due to absenteeism from work due to sickness.
  - The authors concluded that diabetes is a growing economic burden on the social and healthcare systems of Poland.<sup>2</sup>
- In a similar vein of research, Saric et al investigated the cost of diabetes in Croatia and found the actual national burden of diabetes to exceed a conservative estimate of €351 million.<sup>3</sup> Furthermore, the authors of the study concluded that improvements in disease monitoring and prevention of diabetes-related complications would lead to substantial cost-savings in the provision of healthcare for this condition.

In a second Novo Nordisk-sponsored study of the costs of diabetes in Poland, Szmurlo et al assessed the additional cost of adhering to therapeutic goals in patients with diabetes according to treatment recommendations issued by Polish Diabetes (PD), compared with current clinical practice.<sup>4</sup>

- The CORE diabetes model was used to estimate the clinical and economic outcomes of two hypothetical patients; one treated according to current clinical practice and the other according to the PD recommendations.
- The authors concluded that treatment of T2D in accordance with PD recommendations may be cost-effective compared with standard treatment, provided that additional annual costs per patient do not exceed €722.<sup>4</sup>

The cost-effectiveness of intensifying therapy to achieve treatment goals in patients newly diagnosed with T2D was also explored by He et al (Janssen Global Services), for patients younger than 50 in the Swedish setting.<sup>5</sup>

- The group used the Economic and Health Outcomes Model of T2D to compare the cost-effectiveness of a 'treat to goal' strategy versus 'usual care in Sweden,' and found that treating patients according to HbA<sub>1c</sub>, systolic blood pressure and LDL cholesterol targets resulted in QALY gains and net medical cost savings.<sup>5</sup>
- The improvements in health outcomes were attributed to reductions in the cumulative incidences of macrovascular complications. The reduction in costs associated with treating diabetes-related vascular complications more than offset the higher spending on glucose-lowering, anti-hypertensive and lipid-lowering therapies associated with the 'treat to goal' strategy.<sup>5</sup>

### Cost and Cost-Effectiveness Studies of Specific Therapies in the Management of Diabetes

Two posters sponsored by Eli Lilly evaluated healthcare resource use in patients with T2D treated with the glucagon-like peptide-1 (GLP-1) receptor agonist exenatide. Theodorakis et al presented 6-month data from the prospective, observational, 24-month cohort CHOICE study of resource use in patients with T2D who initiated exenatide twice daily (ExBID) or starter insulin (INS) therapy across 6 European countries.<sup>6</sup>

- Overall, 2,492 eligible patients were recruited; 47.2% of patients initiated ExBID and 52.8% initiated INS.<sup>6</sup> The proportions of patients who underwent significant treatment changes over 6 months were similar in the two cohorts (22.0% and 22.5% of the ExBID and INS cohort, respectively).

In the ExBID cohort, there was little change in the proportion of patients using self-monitoring of blood glucose (SMBG), and a small decrease in the mean number of SMBG test strips used per week. In contrast, the proportion of patients using SMBG in the INS cohort rose from 79.8% to 92.4% over the 6-month period; the mean number of SMBG tests used per week and contacts with HCPs also increased by a greater amount than in the ExBID cohort.<sup>6</sup>

The second poster presentation sponsored by Eli Lilly (Wilson et al) calculated the projected cost-effectiveness of exenatide once weekly (ExQW) or exenatide twice daily (ExBID) for the treatment of T2D from the perspective of the UK NHS.<sup>7</sup>

- The published and validated IMS CORE diabetes model was used to make 50-year projections of clinical and cost outcomes based on pooled DURATION-1 and DURATION-5 baseline patient characteristic data and study results.
- The study found that ExQW was projected to be dominant versus ExBID due to greater QALY gains and lower direct costs over the 50-year time horizon; this was, in part, due to the lower projected incidence of most diabetes-related complications in the ExQW group. Results were robust to all deterministic sensitivity analyses.<sup>7</sup>

Saxagliptin and sitagliptin have been shown to possess comparable therapeutic profiles in a head-to-head study and mixed treatment comparison; however saxagliptin has a lower acquisition price. Hutchings et al, sponsored by Bristol-Myers Squibb, presented the results of a study into the cost-effectiveness of saxagliptin versus sitagliptin as an add-on therapy to metformin for the management of T2D from the UK NHS perspective.<sup>8</sup>

The cost-utility analysis used the Cardiff Diabetes Model over a 40-year time horizon. Overall, saxagliptin was found to represent a cost-effective additional option for the treatment of T2D as an add on to metformin in patients who have an inadequate response to metformin alone and in whom sulphonylurea is not appropriate.<sup>8</sup>

The majority of these posters, as shown below, were industry-funded, with Roche and Janssen being the main sponsors in this field.

Figure 3: Breakdown of hepatitis C posters by sponsor type

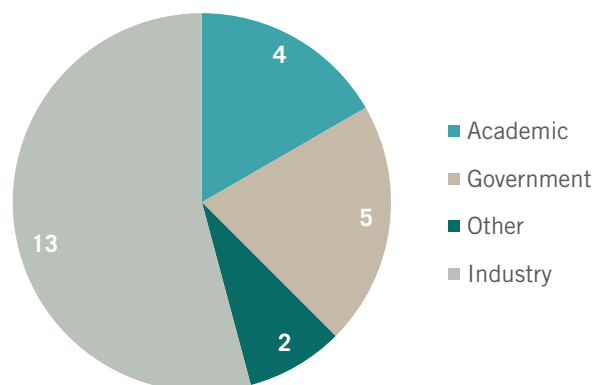
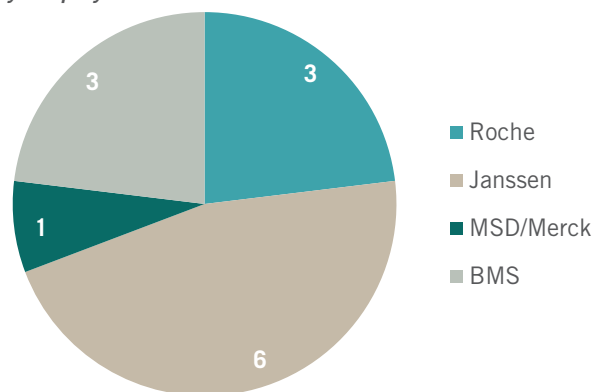


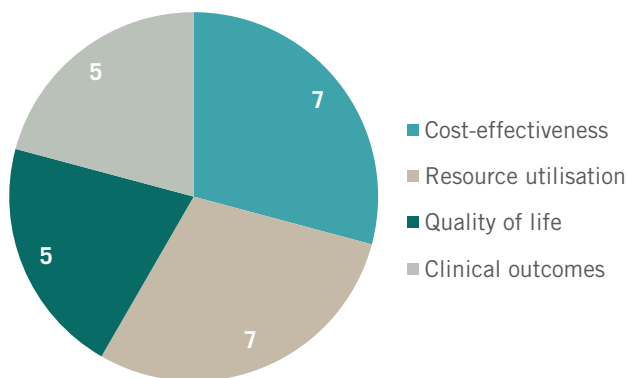
Figure 4: Breakdown of industry-sponsored hepatitis C posters by company



## Poster Research in Hepatitis C

Twenty-four posters were identified that discussed the cost-effectiveness, resource utilisation, quality of life and clinical outcomes in hepatitis C. The distribution of these posters in these topics is shown below:

Figure 2: Breakdown of hepatitis C posters by research topic



## Cost-Effectiveness Analyses

A decision-analytic model was developed to investigate the estimated costs and effects to the Veterans Health Administration (VHA) of hepatitis C virus (HCV) triple therapy with pegylated interferon alfa, ribavirin and boceprevir or telaprevir, compared to standard dual therapy of pegylated interferon alfa and ribavirin (PR) and no treatment.<sup>9</sup>

- Estimated treatment costs associated with dual therapy, triple therapy with boceprevir and triple therapy with telaprevir were \$8,300, \$31,000 and \$45,000 per patient, respectively. This corresponds to system-wide costs of adopting boceprevir and telaprevir of \$673 million and \$971 million, based on a treatment rate of 21%.
- Assuming this 21% treatment rate, the relative reduction in liver-related death compared to no treatment was 5%, 8.7% and 8.4% for dual therapy, triple therapy with boceprevir and triple therapy with telaprevir, respectively.
- Based on these outcomes, boceprevir in combination with pegylated interferon and ribavirin was a more cost-effective treatment strategy compared to the addition to telaprevir.

A cost-utility analysis comparing boceprevir in combination with PR to PR alone found ICERs in the range of £5,249 to £13,300 for the addition of boceprevir to standard therapy in the Scottish national health service (NHS) setting.<sup>10</sup> (Sponsored by MSD and Merck)

- The ICERs for treatment experienced patients (£5,249 and £6,684 for response guided therapy and for 48 weeks of treatment, respectively) were considerably lower than those for treatment naive patients (£6,462 and £13,300 for response guided therapy and for 48 weeks of treatment, respectively).

A cost-effectiveness analysis of pegylated interferon plus ribavirin compared to no antiviral treatment for elderly patients in Japan found an ICER of approximately 2.869 million yen/QALY, translating to approximately €24,950/QALY.<sup>11</sup>

Pharmacoeconomic analyses comparing pegylated interferon alfa 2a + ribavirin to pegylated interferon alfa 2b + ribavirin in Portugal,<sup>12</sup> Russia,<sup>13</sup> and Poland<sup>14</sup> found that pegylated interferon alfa 2a was a highly cost-effective or dominant treatment strategy in these settings. (Sponsored by Roche<sup>12, 14</sup>)

A multidisciplinary support programme (MSP) compared to conventionally controlled patients in the Spanish NHS setting, treating patients with pegylated interferon alfa 2a plus ribavirin, found higher treatment compliance and dominant cost-effectiveness results for the MSP group.<sup>15</sup> (Sponsored by Roche)

## Healthcare Resource Utilisation

Several country-specific studies found that chronic hepatitis C (CHC) is associated with high rates of healthcare utilisation, with the management of long-term consequences and specialised care driving these costs. Therefore, more effective therapies could potentially result in cost savings by reducing severe complication rates.

- A study based on a literature review and clinical expert interviews found that in Sweden, medical resource utilisation and costs increased considerably with more severe disease, ranging from €300 per patient per year for mild CHC to €13,000 for decompensated cirrhosis, €20,000 for hepatocellular carcinoma (HCC) and €120,000 for the first year after liver transplantation.<sup>16</sup> (Sponsored by Janssen)
- In the French Hospital System, 84% of HCV-related hospital costs could be attributed to advanced liver diseases, with 19% of costs corresponding to the 2% of patients receiving liver transplants.<sup>17</sup> (Sponsored by Janssen)

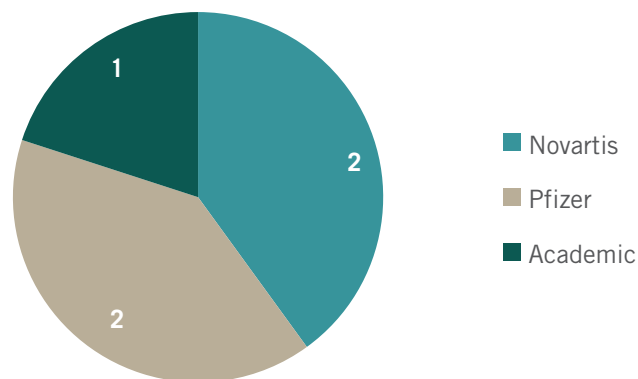
- Total treatment costs in Germany based on following HCV guidelines showed that especially optimal and viral response guided pharmaceutical costs are very high for HCV infection.<sup>18</sup>
- In Belgium, in CHC genotype I patients, cost of care increased with disease stage, except for patients with compensated cirrhosis with varices, who had lower drug and hospitalisation costs compared to patients with mild and moderate disease without varices.<sup>19</sup> (Sponsored by Janssen)
- In a Dutch analysis of 134 genotype I patients, mean direct costs were higher for treated than for non-treated patients, and costs after stopping treatment dropped off after the first 6 months only for patients achieving a sustained viral response.<sup>20</sup> (Sponsored by Janssen)

Treatment-emergent comorbidities in an insured US CHC cohort were common with 61.6% of patients experiencing at least 1 event, and increased direct treatment costs by 25%, equating to \$6,377.<sup>21</sup> (Sponsored by BMS)

## Poster Research in Renal Cell Carcinoma

Five posters were presented on renal cell carcinoma, the majority of which were sponsored by industry (see Figure 5). Both Pfizer and Novartis funded 2 studies each, indicating that both companies have a keen interest in this disease area. The industry posters all focussed on the economic evaluation of therapies for renal cell carcinoma, whereas the academic poster reported results from a Dutch registry.

Figure 5: Funding Sources of Studies Reporting on Renal Cell Carcinoma



## Economic Evaluation of Therapies

Four posters, all sponsored by the pharmaceutical industry, discussed the economic evaluation of therapies in renal cell carcinoma.

- A cost-effectiveness study that was sponsored by Pfizer concluded that sunitinib first-line treatment for renal cell carcinoma was cost-effective compared to sorafenib, but not compared to IFN-alpha in a Chinese setting, when a willingness to pay threshold of ¥66,000 was employed.<sup>22</sup>
- A methodology poster, which was also sponsored by Pfizer, reported that novel statistical approaches, such as parametric Weibull modelling, can help to elucidate the relationship between progression-free survival and overall survival.<sup>23</sup> Based on data from sunitinib and IFN-alpha in renal cell carcinoma, it was demonstrated that progression-free survival can, in some cases, be used as a surrogate endpoint for overall survival.<sup>23</sup>
- In the Brazilian setting, Novartis reported that everolimus was the lowest cost option compared to sunitinib, sorafenib or temsirolimus for the second-line treatment of renal cell carcinoma, when direct healthcare costs of the management of treatment-associated adverse events were estimated.<sup>24</sup>
- The second study funded by Novartis was a cost-effectiveness evaluation of everolimus vs. best supportive care (BSC) alone for the treatment of metastatic renal cell carcinoma patients who had failed one prior VEGF-TKI therapy.<sup>25</sup> The authors concluded that, in this scenario, everolimus treatment was cost-effective in the Canadian setting, with an ICER of \$48,507 per QALY gained compared to BSC alone.<sup>25</sup>

## Healthcare Resource Utilisation

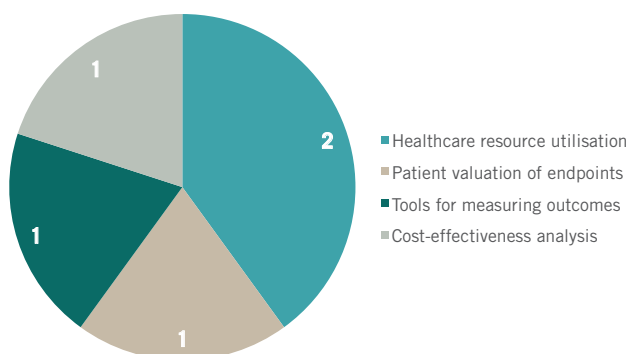
Two posters were presented on a retrospective analysis funded by Teva Pharmaceuticals which investigated treatment patterns and resource utilisation in the US associated with the use of rasagiline or selegiline for the treatment of PD. An administrative claims database (US i3 LabRx) was used to assimilate data on inpatient, outpatient and prescription drug claims from 926 patients initiated on rasagiline and 316 patients initiated on selegiline between January 2006 and December 2010.

- In PND37, Grubb et al. found that there were no significant differences between the percentages of patients on the two medications requiring emergency room visits and hospitalisation in the year post-medication initiation.<sup>26</sup> However, while patients treated with selegiline were significantly less likely to visit a neurologist than patients on rasagiline (89.24% vs. 93.63%;  $p < 0.05$ ), they had a significantly higher mean number of hospital visits (2.94 vs. 1.58;  $p < 0.05$ ) and had significantly longer hospital stays (33.12 days vs. 18.7 days;  $p < 0.05$ ).
- Length of hospital stay was also discussed by Grubb et al. in PND60.<sup>27</sup> However, the primary focus of this research was treatment patterns between the two medication groups. It was determined that patients treated with rasagiline had significantly better medication adherence than those treated with selegiline in terms of medication persistence (259.3 days for rasagiline vs. 229.2 days for selegiline;  $p < 0.05$ ). Patients treated with rasagiline were also significantly less likely to have gaps in their therapy, defined as at least 30 days of non-use of the ITT medication (0.86% vs. 2.85%;  $p < 0.05$ ).

## Poster Research in Parkinson's Disease

Five posters were presented on Parkinson's disease (PD) at ISPOR Madrid, 2011. All were industry-sponsored: two posters were funded by Teva Pharmaceuticals (PND37 and PND60), while Medtronic, Novartis and GSK all funded one poster each (PMD59, PMH47 and PND32, respectively). The major research topics covered are displayed in Figure 6.

Figure 6: Breakdown of PD posters by research topic



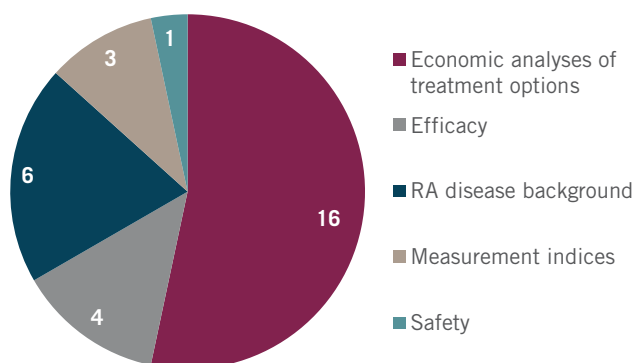
## Cost-Effectiveness Analysis

The only economic analysis presented was a cost-utility analysis funded by GSK (PND32).<sup>28</sup> This compared the cost-utility and cost-effectiveness of ropinirole with that of levodopa and piribedil for the treatment of PD in Poland. A comparison of the monotherapies was conducted, as well as a comparison of combination interventions added to levodopa. It was found that ropinirole generated more QALYs than levodopa and piribedil monotherapy, while ropinirole and levodopa combination therapy generated more QALYs than levodopa therapy alone. In addition, ropinirole was more cost-effective than the comparator monotherapy treatments, and ropinirole as an add-on therapy to levodopa was more cost-effective at higher doses.

## Poster Research in Rheumatoid Arthritis

A great deal of data was presented on Rheumatoid Arthritis (RA) at the 14th European ISPOR Congress 2011. We identified 30 posters that were of particular interest in our analysis of the available data. As can be seen in Figure 7 below, the majority of these posters considered economic aspects of RA treatment. These included cost-utility analyses, cost-effectiveness analyses, and budget impact models. A number of abstracts, many of which were supported by academic institutions, also investigated aspects of disease background, such as comparisons of the experience of RA patients across the world, and discussions of the burden of RA in general.

Figure 7: Topics covered in posters on RA that were presented at ISPOR



Of these abstracts, we have selected some key posters for further discussion. An analysis of the data presented in these posters is provided below.

### Economic Analyses of Treatment Options

Pfizer sponsored 3 economic analyses on the use of Etanercept (ETN); these were conducted in Columbia, Brazil and Venezuela.<sup>29-31</sup>

- The studies compared use of ETN to Adalimumab (ADA) and Infliximab (IFX) in the countries of interest, the Venezuelan study also compared ETN to Tocilizumab (TCZ) and Rituximab (RTX).
- The Venezuelan and Columbian analyses found that ETN was the dominant treatment strategy in each of their respective healthcare systems, as it resulted in lower costs, along with better ACR70 responses and QALY gains than the alternative strategies tested.
- In the Brazilian model, ETN was shown to exhibit incremental clinical effectiveness at a lower cost per ACR70 responder compared to ADA or IFX. The effect on utility was not analysed.

A further 2 posters were presented on Certolizumab pegol (CZP) sponsored by UCB.<sup>32, 33</sup>

- The first discussed the cost-effectiveness and budget impact of using CZP+MTX in Greece. The analysis indicated that CZP+MTX was cost effective compared to any of ADA, ETN or IFX in combination with MTX. In terms of budget impact, the introduction of CZP into the Greek market was forecast to result in net savings of €7.68 million over 2011-2015.<sup>33</sup>
- In a cost-utility analysis from the Spanish perspective, CZP with MTX was found to be cost-effective versus ETN, ADA, IFX, the other available anti-TNFs in Spain.<sup>32</sup>

A model of RTX in patients from the Netherlands who had failed a prior anti-TNF was also presented.<sup>34</sup>

- In the Netherlands, RTX, Abatacept (ABA) or a second anti-TNF are generally given in daily practice after one anti-TNF failure. Patients can be given other biologics or DMARDs if these treatments also fail. (This was defined as 'palliative care' in the model presented).
- Three treatment protocols were investigated:
  - The RTX strategy: RTX+MTX, followed by an anti-TNF inhibitor (ADA)+MTX, followed by TCZ, followed by palliative care.
  - The ABA strategy: ABA+MTX, followed by an anti-TNF inhibitor (ADA)+MTX, followed by TCZ, followed by palliative care.
  - A TNF-Cycling strategy: an anti-TNF inhibitor (ADA)+MTX, followed by TCZ, followed by palliative care.
- The RTX strategy was predicted to dominate other methods of treatment for patients who had failed one anti-TNF in the Dutch setting, making this an important cost-saving intervention.

The cost-effectiveness of TCZ was investigated in Portugal. A Markov model was created to investigate the effect of different treatment strategies in 10,000 hypothetical patients with moderate/severe RA who were DMARD non-responders. In each of the three scenarios tested, a treatment sequence initialised with TCZ, followed by an anti-TNF, then RTX, then ABA, then supportive care was compared to the same sequence initialized with an anti-TNF instead of TCZ.<sup>35</sup>

- The model consistently predicted that initial treatment with TCZ in DMARD non-responders was dominant over treatment strategies initiated with an anti-TNF. The authors reached the conclusion that TCZ allowed "important gains in health and significant cost-savings for society".

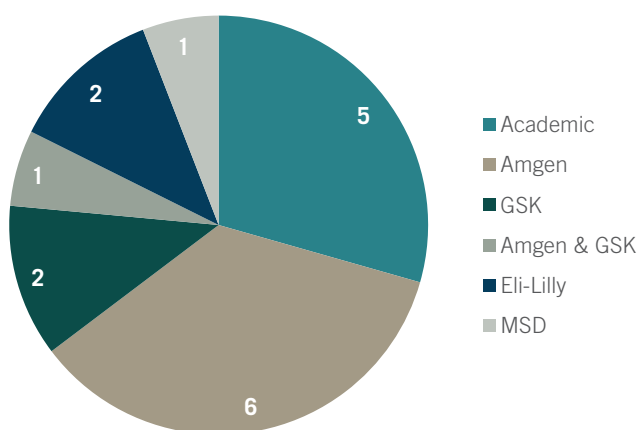
Data on the cost and cost-effectiveness of ABA was also presented.

- A trial-based real-life cost-consequence analysis of ABA and IFX was presented.<sup>36</sup> The cost-consequence analysis was favourable for ABA once patients in low disease activity or disease remission had reached the maintenance stage of their illness, making ABA an attractive option for long-term treatment of these patients when compared to IFX.
- In a budget impact analysis, it was noted that the use of ABA as a first line biologic treatment for RA provided better disease control and lower total costs compared to ADA and ETN in Italy.<sup>37</sup>
- A cost-effectiveness study from the UK perspective noted that, compared to conventional DMARDs, ABA had a probability > 50% of being cost effective at a willingness to pay threshold of £30,000.<sup>38</sup>

## Poster Research in Osteoporosis

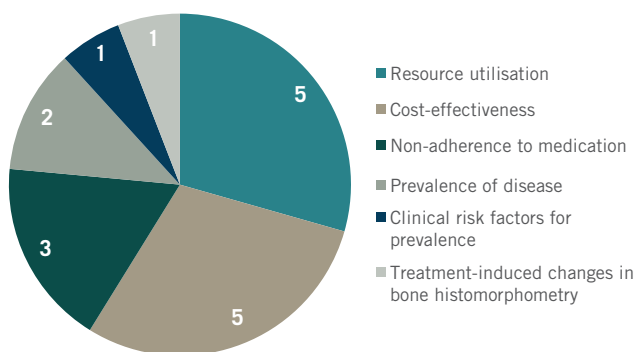
There were 17 posters on osteoporosis presented at ISPOR Madrid, 2011. The breakdown of these posters by sponsor is displayed in Figure 8. It can be seen that 12 studies were industry-funded, with Amgen funding the largest number of publications.

Figure 8: Breakdown of osteoporosis posters by sponsor



The main topics of research in this disease area were healthcare resource utilisation and cost-effectiveness models. The number of abstracts presented on each topic is presented in Figure 9.

Figure 9: Breakdown of osteoporosis posters by research topic



## Healthcare Resource Utilisation

Amgen funded two retrospective studies assessing the utilisation of healthcare resources by patients with postmenopausal osteoporosis (PMO) in Slovenia, Serbia and Bulgaria. The first study (PMS27)<sup>39</sup> additionally included Slovakia, and evaluated resource use and costs of treatment for osteoporotic patients without fractures, while the second (PMS28)<sup>40</sup> considered only patients with osteoporotic fractures.

- In PMS27, Rutkowski et al analysed hospital data between July 2010 and April 2011 for 410 females aged  $\geq 50$  years with a diagnosis of osteoporosis and no history of fracture.<sup>39</sup> Usage and costs were ascertained for three main resource areas: laboratory tests and examinations, outpatient visits and drugs (only drug costs were calculated for Bulgaria). The cost of drugs constituted the majority of total treatment costs in the countries evaluated, accounting for 82.6% of the total cost of treatment in Slovenia, and 93.0% of total costs in Serbia and Slovakia. Annual mean outpatient costs of treatment for PMO in Slovenia, Serbia, Slovakia and Bulgaria were €384, €190, €491 and €590 respectively. This included total costs for both the public payer and the patient.
- In PMS28, Rutkowski et al analysed the utilisation of healthcare resources and direct medical costs of 656 patients with postmenopausal osteoporotic fractures in the first and subsequent years after the fracture.<sup>40</sup> Only the most common and costly fractures were included (proximal femur, vertebral and distal radius). Unlike in PMS27,<sup>39</sup> the costs of osteoporosis medications and supplements were not included. It was determined that proximal femur fracture resulted in the highest utilisation of resources and costs of treatment in Slovenia, Serbia and Bulgaria. The mean two-year cost of treatment of a low-energy proximal femur fracture as a percentage of annual GDP per capita was 28% in Slovenia (€4,463) and 93% in Serbia (€3,277). The greatest costs were generally incurred in the first year after the event, but treatment costs in subsequent years were also substantial.

Two further studies funded by Amgen highlighted the extensive healthcare resource utilisation and economic burden of osteoporosis:

- Athanasakis et al (PMS19) constructed an expert-validated disease management model, which was based on structured interviews with 137 physicians to illustrate the direct medical costs of postmenopausal osteoporosis in Greek women.<sup>41</sup> The cost variables included the costs of consultations, laboratory tests, anti-osteoporotic medication, dietary supplements, hospitalisation and rehabilitation, all calculated from a third-party payer perspective for a one-year timeframe. It was determined that the direct medical costs of treating PMO in Greece could be estimated at €890 million, based on a prevalence of osteoporosis in women over 50 years of 28.4%.
- Tarride et al (PMS22) estimated the burden of osteoporosis among Canadians aged 50 and over from payer and societal perspectives.<sup>42</sup> They assimilated data from the Canadian Institute for Health Information on hospitalisations, emergency visits, same day surgery, rehabilitation, home care, continuing care and long-term care. Osteoporosis-related fractures were estimated to be responsible for 57,413 hospitalisations, 112,740 emergency room visits and 3,433 same day surgeries in 2007/2008. The overall annual cost of osteoporosis was over \$2.3 billion for the base case analysis, rising to \$3.9 billion when a proportion of Canadians were assumed to be living in long-term care facilities due to osteoporosis.

- In Spain, denosumab was found to be cost-effective in the prevention of osteoporotic fractures compared to all comparators, and it was the dominant treatment option compared to strontium ranelate, being both more effective and less costly.<sup>45</sup>
- In Scotland, denosumab was shown to be cost-effective compared to raloxifene, no treatment and IV ibandronate in both the base case and all sensitivity analyses. Denosumab dominated strontium ranelate. Zoledronate was also found to be not cost-effective compared to denosumab.<sup>44</sup>

A study by Tilden et al (PMS41) and funded by MSD assessed the cost-effectiveness of expanding access to alendronate for the prevention of osteoporotic fractures in Australia.<sup>46</sup> Specifically, it considered broadening the provision of alendronate to patients with a prior fracture or those aged  $\geq 70$  years with a bone mineral density (BMD) T-score of  $\leq -2.5$  (current access is restricted to those patients with a BMD T-score of  $\leq -3.0$ ). A cost-utility analysis demonstrated that this would prevent fractures and result in fewer fracture-associated deaths compared to current Australian practice, at an incremental cost per QALY of AUD34,808.

### Cost-Effectiveness Studies

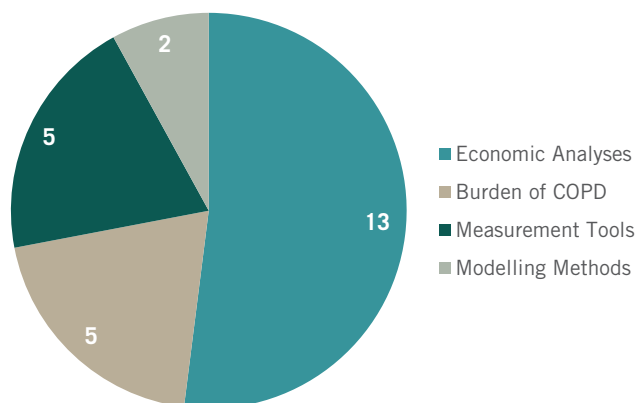
Three studies sponsored by Amgen all investigated the cost-effectiveness of denosumab for the treatment of PMO in Greece (PMS35),<sup>43</sup> Scotland (PMS44)<sup>44</sup> and Spain (PMS48).<sup>45</sup> The same validated Markov cohort model was used in each analysis, with the objective in the Spanish and Greek analyses being to compare the cost-effectiveness of denosumab with that of generic alendronate, branded risedronate, ibandronate, strontium ranelate and no treatment. In contrast, the Scottish analysis aimed to assess the cost-effectiveness of denosumab in the prevention of osteoporotic fractures in postmenopausal women unsuitable for oral bisphosphonates; the comparators were no treatment, strontium ranelate, raloxifene, IV ibandronate and zoledronate.

- In the Greek analysis, denosumab was found to be more costly but more effective than all comparators in terms of reduced fracture occurrence and QALYs gained.<sup>43</sup> The incremental cost-effectiveness ratios (ICERs) of denosumab compared to all comparators were below the €30,000 per QALY threshold.

## Poster Research in Chronic Obstructive Pulmonary Disease

The majority of posters relating to Chronic Obstructive Pulmonary Disease (COPD) were economic analyses, with multiple abstracts on indacaterol and roflumilast. Other topics included the burden of COPD, assessment of measurement tools, and modelling methods (Figure 10).

Figure 10: Breakdown of COPD posters by research topic



## Economic Analyses

There were thirteen posters analysing the economic data covering various COPD therapies. Of the five Novartis-sponsored posters, two investigated the budget impact analysis of indacaterol, two examined the cost-effectiveness of indacaterol and one examined the cost savings associated with adhering to recommended COPD management guidelines. Moreover, three posters sponsored by Nycomed Pharma examined the cost-effectiveness of roflumilast in three European countries. In addition, the cost-effectiveness of available treatment options in the UK setting was presented, along with an economic analysis of tiotropium treatment in France. Finally, three posters by GSK; two evaluating fluticasone and one examining the cost of Global Initiative for COPD (GOLD) program recommendation uptake in Italy.

- The two budget impact analyses conducted by Novartis examined the impact of introducing indacaterol in Brazil, one from the public payer perspective and one from the public healthcare system perspective. From the public payer perspective, the introduction of indacaterol has the potential to reduce costs on the budget of the state public healthcare system.<sup>47</sup> From the public healthcare system perspective, the annual investment for introducing indacaterol would be around R\$21 million.<sup>48</sup>
- Of the two Novartis-sponsored cost-effective analyses of indacaterol in comparison to tiotropium and formoterol, a study in Brazil found that indacaterol was cost saving compared to tiotropium (incremental cost R\$-2,667).<sup>49</sup> Compared to formoterol, the projected ICER was R\$25,458 (\$14,408) per life year gained. A similar result from a study conducted in Greece found that indacaterol represents a cost-effective treatment compared to both tiotropium and formoterol.<sup>50</sup>
- Four analyses evaluated the cost-effectiveness of roflumilast. Three were conducted by Nycomed Pharma: one in Spain, one in Sweden and one in Switzerland. The other analysis was sponsored by MSD Ltd.
  - The Spanish evaluation concluded that roflumilast + long-acting muscarinic antagonist (LAMA) was a more cost-effective treatment for severe COPD as compared to LAMA + long-acting beta antagonist/inhaled corticosteroid (LABA/ICS).<sup>51</sup>
  - Similarly, roflumilast was considered a cost-effective treatment for severe COPD in Sweden in various comparator scenarios, as compared to other relevant treatment options.<sup>52</sup>
  - Roflumilast was also found to be a cost-effective treatment option for COPD patients in Switzerland, reducing the number of exacerbations in COPD patients.<sup>53</sup>
- MSD Ltd sponsored a full incremental analysis, examining the cost-effectiveness of available treatment options in the UK. It evaluated the lifetime costs and outcomes of adding roflumilast to LAMA, LABA, and the combination of LABA/ICS or combinations of these regimens, using a Markov model. It was concluded that whilst LAMA is recommended as an initial treatment, the addition of roflumilast to standard care is an effective treatment option, providing an alternative treatment for those with severe COPD whose symptoms continue to exacerbate.<sup>54</sup>
- An academic collaboration evaluated the cost-effectiveness of tiotropium and pulmonary rehabilitation programs compared to usual care in French COPD patients. A Markov model was developed to simulate outcomes in the studied population (106 patients), forecasting until death. The ICERs were €9,215/QALY and €12,000/QALY, for tiotropium and pulmonary rehabilitation programs respectively. It concluded that both treatments were cost-effective, providing moderate health gains for COPD patients over usual care.<sup>55</sup>
- Novartis, in collaboration with US universities, sponsored a study to estimate the potential cost savings and reduction in exacerbations by following guideline recommendations. It concluded that adherence to current GOLD guidelines is associated with lower costs and fewer exacerbations in subjects with moderate to severe COPD for LAMA+LABA, LABA+ICS and LAMA+LABA/ICS groups.<sup>56</sup>
- Three posters by GSK examined the economic data surrounding COPD therapies, including two on fluticasone (the impact of regional data on cost-effectiveness results,<sup>57</sup> cost-utility of fluticasone<sup>58</sup>) and one on the cost of universal GOLD recommendation uptake in Italy.<sup>59</sup>

## Clinical Burden of COPD

Three reports discussed the economic burden of COPD.

- A poster produced by an academic team in Sweden established the cost of COPD by disease severity. It was concluded that the costs are high in Sweden and the costs increase considerably with disease severity. The total costs for Sweden could be estimated to be €1.2-1.5 billion, with indirect costs accounting for approximately 70% of the total costs.<sup>60</sup>
- Two academic posters from Ukraine also inspected the costs associated with COPD. The first retrospectively analysed the direct and indirect costs associated with the disease, concluding

that the costs associated with COPD are large, amounting to €38,870,506 in 2009, with direct medical costs accounting for 73.18% of this total.<sup>61</sup> This is a different finding to the Swedish study above and the reason for this discrepancy is unclear. The second poster evaluated the medication costs in Ukraine, estimating that the total cost associated with treating COPD was €54,449,429.<sup>62</sup>

## Modelling Methods

One poster by GSK provided a systematic literature review of conceptual models to inform economic modelling in COPD. It was concluded that the available evidence does not provide a full spectrum of the relationships between diagnosis, progression and outcomes needed for a comprehensive based economic model in COPD.<sup>63</sup> In addition, a poster sponsored by Novartis assessed the applicability of innovative modelling methods (Latent Growth Modelling (LGM) and Growth Mixture Modelling (GMM)) to COPD clinical trial data to identify and characterise unobserved groups of differential responders.<sup>64</sup> The two analyses successfully identified variability, and were able to model subsets of differential responders. The authors concluded that this methodology could be applied to other endpoints in COPD, and further prospective testing is needed to assess the ability of the models to predict outcomes from baseline characteristics.

## Economic Analyses

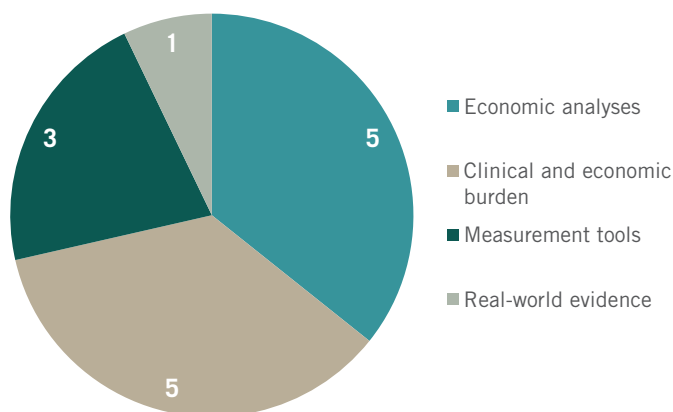
There were seven studies identified covering economic analyses. Two posters sponsored by Novartis evaluated the cost-effectiveness of omalizumab in Australia and The Netherlands compared to optimised asthma therapy and standard care respectively. Similarly, a study in Thailand analysed the cost-utility of omalizumab compared to standard medical treatments. An additional analysis sponsored by academia evaluated the cost-effectiveness of the step down from high dose ICS/LABA in the UK setting. Finally a budget impact analysis, conducted by Spanish academia, estimated the economic impact of beclomethasone/formoterol.

- There were two posters sponsored by Novartis concerning the cost-effectiveness of omalizumab in the Australian and Dutch settings. The first study in Australia was conducted to identify the patient population where the treatment of severe allergic asthma with omalizumab exhibits optimal cost-effectiveness.<sup>65</sup> Patients from two RCTs were analysed to identify subpopulations where the cost-effectiveness of omalizumab was the greatest, as compared to optimised asthma therapy. It concluded that the patients in which omalizumab was most cost-effective were those using a maintenance oral corticosteroid (MOCS) with a baseline ACQ-5  $\geq$  2.0. These patients also had the greatest clinical need for an effective asthma treatment. The second poster sponsored by Novartis compared the results of two cost-effectiveness analyses for omalizumab added to standard therapy in severe allergic asthma patients using an RCT compared to a real-world prospective observational study.<sup>66</sup> The ICERs for omalizumab compared to standard care alone were similar in the two analyses, despite substantial differences in patient characteristics (exacerbation rates and resource use) between the two data sets.
- One poster examined the cost-utility of omalizumab compared to standard medical treatments (ICS, LABA or oral corticosteroid) for severe asthma patients in Thailand.<sup>67</sup> It concluded that omalizumab is not cost-effective and that improving access to ICS and LABA should be the priority for the medical care of asthma in Thailand. In this case, omalizumab was not considered cost-effective as the ICER of 414,503 Baht (US\$13,371) exceeded the 1 GDP per capita threshold for including new health interventions into the universal health coverage scheme benefit package. This reflects the different thresholds between various countries for new therapies.
- A budget impact analysis sponsored by Spanish academia estimated the economic impact of beclomethasone/formoterol for the treatment of moderate to severe persistent asthma in Spanish regions.<sup>68</sup> It discovered that the mean cost per patient was estimated at €996 before

## Poster Research in Asthma

The majority of posters relating to asthma were economic analyses, examining omalizumab, salmeterol/fluticasone and beclomethasone/formoterol. Other posters evaluated the clinical and economic burden of asthma, real world evidence and the assessment of measurement tools.

Figure 11: Breakdown of asthma posters by research topic



the introduction and €990 after the introduction of beclomethasone/formoterol treatment and this reduction in budget impact demonstrated a net saving for all regions over the next 5 years.

- An academia sponsored cost-effectiveness analysis in the UK setting evaluated the step down from high dose ICS/LABA therapy in asthma. This was in accordance to recommendations by the international guidelines on the management of asthma (GINA), which state that step down to the lowest dose of treatment that maintains control should be considered for asthma patients. The study found that using beclomethasone/formoterol reduced the ICER compared both medium and high dose fluticasone/salmeterol. The ICER values of both medium and high fluticasone/salmeterol dosages compared to beclomethasone/formoterol show that the cost per QALY are too high to be considered cost-effective treatments.<sup>69</sup>
- One poster produced by GSK evaluated the Optima model-based cost-utility analysis of salmeterol/fluticasone versus budesonide/formoterol in Russia.<sup>70</sup>

## Real-World Evidence

A study sponsored by Novartis in The Netherlands presented the one-year resource use results from an international registry of real-world outcomes for asthma patients treated with omalizumab.<sup>71</sup> The objectives of the report were to describe the clinical outcomes, healthcare resource utilisation and cost patterns associated with uncontrolled allergic asthma. The study concluded that the average costs of persistent asthma were €4,257 per patient in the year prior to the study and €2,583 per patient during the study year. Therefore, the use of omalizumab decreased the need for hospital admissions, physician visits and the number of working days lost.

## Poster Research in Crohn's Disease

A search of the research findings presented at the European ISPOR Congress 2011 identified a single study of healthcare resource utilisation in Crohn's disease. In order to determine the predictors of direct medical costs of inflammatory bowel disease (IBD), Stark et al<sup>72</sup> recruited 241 Crohn's disease (CD) and 242 ulcerative colitis patients from the German IBD Association to a postal survey in which they were asked to report on healthcare use and medication intake related to their IBD in a cost diary over four weeks.

- A high proportion of CD patients had required surgery previously, and 58% of the CD participants were in remission at the time of the survey.
- Costs of prescribed medications for CD accounted for the highest proportion (over half) of total costs, although costs for hospital admissions and other medical products make up an important proportion of costs for patients with CD.
- Disease activity and disease history (either continuously or intermittently active) were the most important determinants of cost for CD patients. Age and employment status were found to be additional important cost determinants.

## Poster Research in Systemic Lupus Erythematosus

Four posters were presented concerning systemic lupus erythematosus (SLE).

One poster, sponsored by UCB, presented results from the Lupus European Online (LEO) Survey, which examined the impact of SLE on career choices and work productivity in five European countries. The data presented suggested that Lupus diminished the likelihood of European patients working, and impacted on their productivity at work.<sup>73</sup>

GlaxoSmithKline presented 3 studies on costs in SLE:

- The first was a cost impact analysis of corticosteroid-associated adverse events in lupus in the US. The authors estimated that the additional cost of these events was \$784 per year per patient.<sup>74</sup>
- The second study found that the mean annual cost of active lupus was €4,116 per patient in France, a value largely driven by the cost of medication.<sup>75</sup>
- Finally, the cost of care in five European countries (France, Germany, Italy, Spain, and the UK) was analysed. Severe flares, in particular, were found to be associated with higher costs and were identified as overall cost predictors and cost drivers ( $p < 0.001$ ).<sup>76</sup>

## 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 require more information on any of the mentioned research, we can supply you with the abstracts or posters. Alternatively, we can offer to conduct a more detailed literature search on any given topic.

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