ISPOR 20th Annual European Congress, Glasgow 2017

Congress Report

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This year, Glasgow played host to the 20th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

The congress spanned 5 days (4th to 8th November) and attracted nearly 5,000 delegates from Europe and further afield to explore and discuss the main theme of "The Evolution of Value in Health Care", alongside a number of other topics **(Figure 1)**.

Costello Medical sent 17 members of staff to join the ISPOR community at the congress, and are pleased to present our report from the meeting.

This year's report covers four of the key themes from the conference:

- Market access for high-cost transformative interventions
- Patient access, sustainability and challenges in rare diseases
- Evidence requirements and values assessment in medical devices
- Incorporation of patient value in Health Technology Assessment

In addition, our report includes a "Technical Corner" touching on more methodological topics:

- Methodological advances in real-world evidence analysis
- Decision modelling in the evolving therapeutic environment

Figure 1. ISPOR Glasgow 2017 Word Cloud Describing the Key Topics Covered at the Congress

Word cloud generated using terms for key topics as reported by Costello Medical attendees.

Market Access for High-Cost Transformative Interventions

With the advent of advanced therapy medicinal products, including gene, somatic-cell, and tissue-engineered therapies, high-cost transformative interventions were a key theme at the conference this year (it is estimated that there will be more than 70 cell and gene therapy products on the market by 2020).[1] In particular, the pricing and reimbursement challenges associated with high-cost interventions considered to be "curative" were discussed at a number of sessions.

Appraisal of Cell and Gene Therapies versus Traditional Pharmaceuticals

In one interesting issue panel, Clark Paramore (Bluebird Bio) highlighted the challenges associated with bringing cell and gene therapies to market, and their similarities and differences to traditional pharmaceuticals.[1] Ron Akehurst (BresMed Health Solutions), and Adrian Towse (Office for Health Economics) then led a discussion as to whether existing health technology assessment (HTA) requirements are adequate for establishing value for potentially transformative cell and gene therapies.[2,3] Although they differed in their stance on this issue, both panellists agreed that the key factor in the decision-making process would be the innovative pricing mechanisms used to offset the high upfront costs associated with these therapies, such as 'leasing' the therapy for as long as the patient remains alive and asking the patients for formal commitment to further data collection.[1] A poster presented by Spark *et al.* explored several other possible pricing mechanisms that could be implemented to overcome some of the challenges associated with bringing these high-cost cell and gene therapies to market **(Figure 2)**.[4]

Valuing Transformative Therapies

An important challenge for HTA bodies when considering these therapies lies in the valuation of quality adjusted life-year (QALY) gains, given evidence that not all QALYs appear to have the same value. Research showing that community values tend to favour equity over utility supports the idea that costly therapies are acceptable when aimed at end-of-life or rare disease patients.[5] It was also argued that there is an insurance value to society in the availability of these curative treatments.[1] These value judgements may be highly relevant to the consideration of high-cost regenerative therapies. Nevertheless, Adrian Towse argued that when value judgements and trade-offs are made, these should be made explicit.

Figure 2. Possible Payment and Funding Mechanisms to Overcome Market Access Challenges for Cell and Gene Therapies (Adapted from Poster Presentation PHP194)

Challenges	Possible payment and funding model solutions
• Up front high-cost payment whilst benefit/payback is spread over a long time	• **Outcomes-based payment**: 'Money-back guarantee' or payment made per unit of health achieved; administrative burden is the biggest barrier
• Often provided in single specialist centres (cost impact on single centre's budget)	• **Instalment payments**: Provision of a loan, repaid in fixed regular instalments; untested mechanism in the pharmaceutical industry
• Uncertainty around long-term efficacy (what happens if the therapy doesn't work?)	• **Full service payment**: Manufacturer paid fixed sum per patient to cover all care costs; requires substantial investment in new equipment, premises and personnel
• Uncertainty around long-term safety	• **Specialist fund**: Payers create a specialist fund for the explicit use of funding curative cell and gene therapies (e.g. Cancer Drugs Fund)
• Uncertainty around long-term budget impact due to uncertainty of long-term efficacy	• **Prize funding**: Set up by private philanthropists and/or the public sector to promote innovation, with the aim of subsidising research and development and tempering list price on receipt of prize
• High manufacturing and operational costs	• **Reinsurance**: Payer buys re-insurance to minimise financial uncertainty of high payouts for individual patients
• Uncertain cost comparator (should the benchmark be the overall cost of chronic therapy, or similar technologies e.g. stem cell therapy, transplantation)	

Adapted from Poster Presentation PHP194: Paying for Gene Therapies: Approaching a Sustainable Solution. ISPOR 20th Annual European Congress, Glasgow, 2017.[4]

Patient Access, Sustainability and Challenges in Rare Diseases

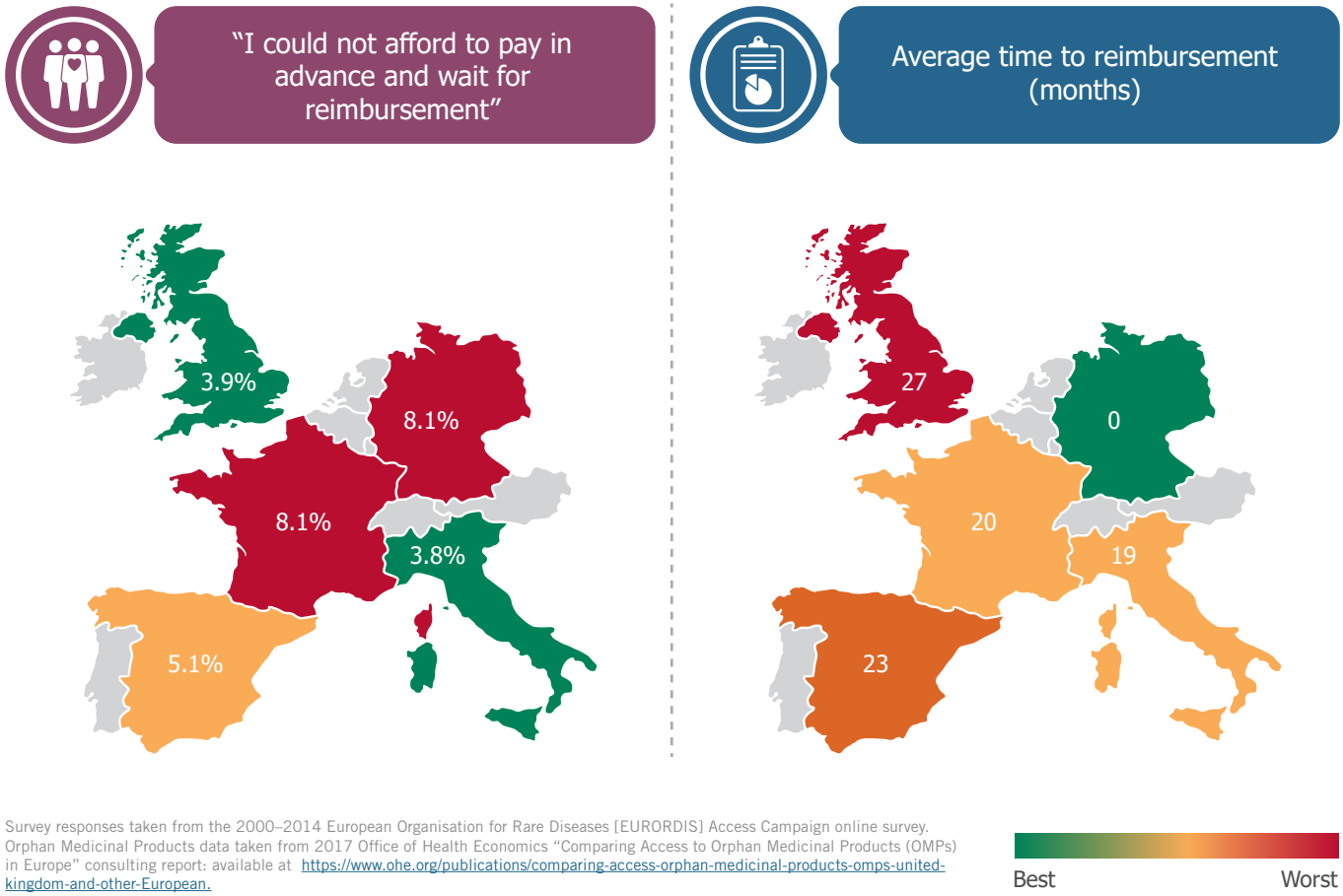
Orphan and ultra-orphan therapies were, once again, a key theme at this year's ISPOR EU, with discussions focussed on developing sustainable long-term solutions to the challenges of pricing and drug development in rare diseases.

European Consistency

A workshop discussing sustainable funding and fair pricing for orphan drugs was led by Martina Garau (Office of Health Economics).[6] Martina Garau initiated discussions by presenting results of a Shire-sponsored study that highlighted the considerable variation in access to Orphan Medicinal Products (OMPs) across Europe.[6, 7] For example, Germany enabled access to 93% (133/143) of centrally authorised OMPs and reimbursement for these products is granted automatically. On the other end of the scale, in England only 47.6% (68/143) of the licensed OMPs were reimbursed and the average time to a reimbursement decision was 27.6 months.

The results of the study were compared to the findings of an ongoing EURODIS patient access survey in a podium presentation by Aimée Hall (Costello Medical).[8, 9] This presentation flagged striking discrepancies between patient opinion on access to treatments and indicators such as time to reimbursement; in the UK, although patients experienced the longest waiting times for a reimbursement decision, only 3.9% of surveyed patients reported that they "could not afford to pay in advance and wait for reimbursement" **(Figure 3)**. The topic of European consistency was also the focus of an issue panel led by Lieven Annemans (University of Ghent), which discussed the application of the ORPH-VAL principles in Germany, France and the UK.[10] The 9 ORPH-VAL principles were developed by the European Working Group for Value Assessment and Funding Processes in Rare Disease and published earlier this year.[11] An EU-wide assessment of orphan drugs was proposed as a more efficient and aligned approach, although it was acknowledged that value-for-money decisions should be considered at a country level.

Figure 3. Patient Reported Time to Reimbursement (Adapted from Podium Presentation SY4)



Survey responses taken from the 2000–2014 European Organisation for Rare Diseases [EURORDIS] Access Campaign online survey. Orphan Medicinal Products data taken from 2017 Office of Health Economics "Comparing Access to Orphan Medicinal Products (OMPs) in Europe" consulting report: available at https://www.ohe.org/publications/comparing-access-orphan-medicinal-products-omps-united-kingdom-and-other-European.

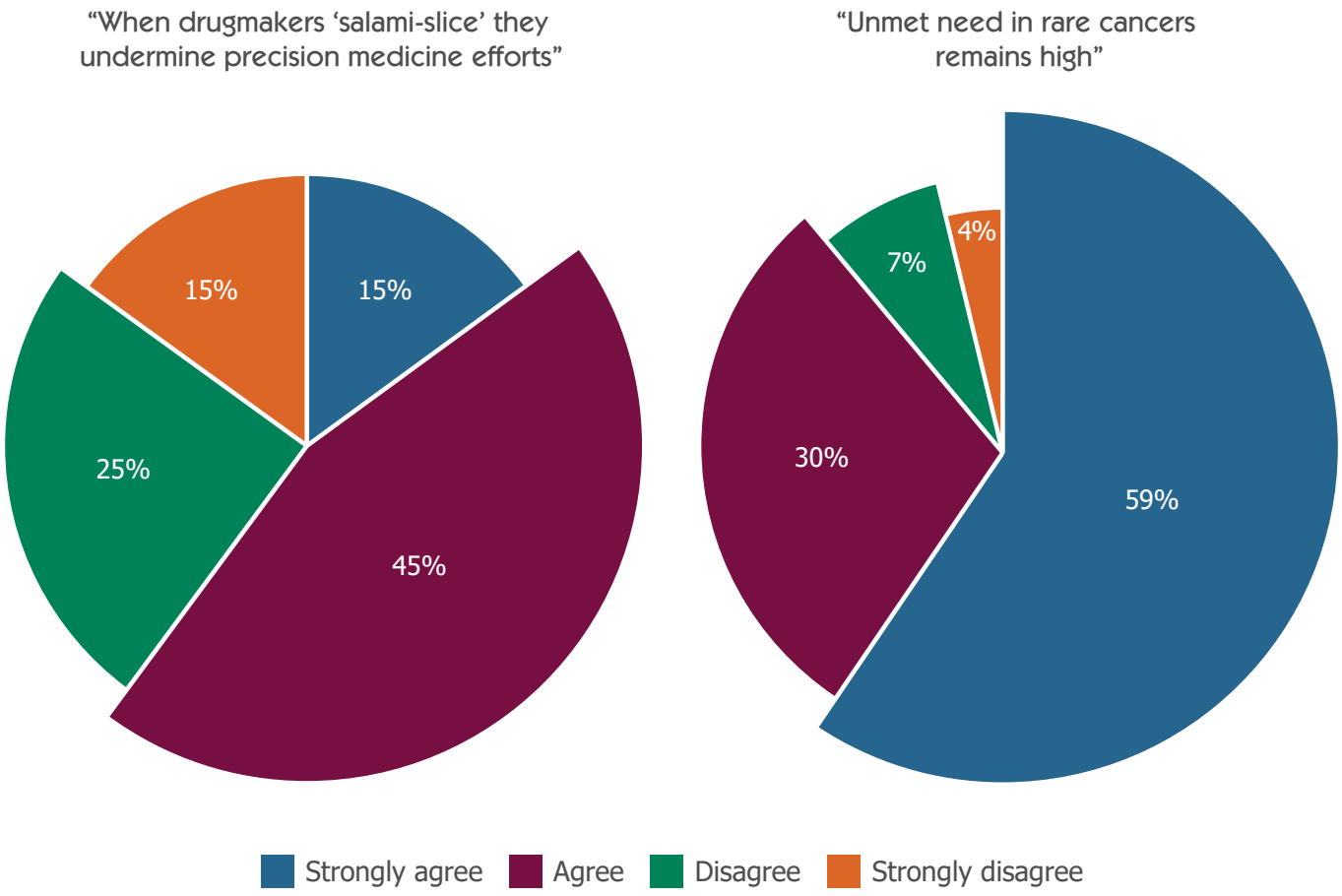
Adapted from Podium Presentation SY4: Do EU5 Countries with Favourable Healthcare Expenditure and Reimbursement Indicators Have Better Patient-Reported Access to Treatments for Rare Diseases? ISPOR 20th Annual European Congress, Glasgow, 2017.[8]

Sustainability in Orphan Drug Development and Pricing

During the previously mentioned workshop on sustainable funding and fair pricing, Mike Drummond (Centre for Health Economics) shared preliminary findings of ongoing work to establish a reasonable price for orphan drugs.[6] The research aimed to determine adjusted cost-effectiveness thresholds for orphan and ultra-orphan medicines, based on estimated research and development costs, whilst also making a distinction between oncological and non-oncological treatments. Such work is particularly relevant considering the revisions to the National Institute for Health and Care Excellence (NICE) highly specialised technologies (HST) programme and the introduction of a moving threshold that is dependent on a QALY modifier.[12]

The question of whether treatments for rare cancers should be considered true orphans was discussed in an issue panel moderated by Annabel Griffiths (Costello Medical).[13] The session began with an audience vote on two statements relating to this issue **(Figure 4)**. Stakeholder representatives then discussed the arguments for and against the inclusion of rare oncology treatments within the orphan and ultra-orphan umbrella from the perspectives of industry, patients and HTA bodies. The common challenges of R&D in rare diseases and rare cancers were highlighted, and the value of the "orphan" label considered. Drug repurposing as an alternative but less supported method of drug development for rare cancers was discussed, raising the question of whether it is time to reconsider incentives in rare diseases. Finally, it was agreed that a separate reimbursement process for rare oncology treatments would not add further value.

Figure 4. Rare Oncology Treatments as True Orphans - Results of Audience Vote



Adapted from Issue Panel IP9: Should Rare Oncology Treatments be Considered True Orphans? ISPOR 20th Annual European Congress, Glasgow, 2017.[13]

Evidence Requirements and Value Assessment in Medical Devices

The key theme for medical devices at this year's meeting was the changing evidence requirements for regulatory approval and reimbursement, and how this may affect patient access to novel devices.

Impact of Higher Evidence Requirements on Manufacturers

Two new medical device regulations (2017/745 and 2017/746) were adopted by the European Parliament and the European Council in April 2017.[14] These new regulations introduced higher clinical evidence requirements for CE marking, particularly for higher-risk devices. This ensures patient safety,[14] but there is a danger they may disincentivise innovation and delay patient access.[15, 16] In the field of mobile health applications, regulatory representatives expect that the new regulations will result in greater trust in such applications amongst clinicians and patients, causing uptake to increase. In line with discussions at previous ISPOR meetings, industry representatives re-emphasised that device manufacturers need to proactively invest in pre-market clinical programmes to meet the evidence requirements for regulatory approval and, thereby avoid delaying patient access.[15]

Accelerated Patient Access through Managed-entry Schemes

Managed-entry schemes – short-term reimbursement agreements conditional on data collection to allow re-evaluation of effectiveness – were a widely supported solution to avoid delays in patient access to novel devices if there remains uncertainty in clinical outcomes.[15, 17] Manufacturers and payers agreed these schemes would be valuable under specific circumstances, for example if the device's medical benefit is expected in the longer-term (e.g. for a chronic illness) and therefore challenging to demonstrate in a clinical trial programme. These schemes require payers and manufacturers to work together to collect data measuring device performance, and to agree on exit strategies if the agreed outcomes are not met. However, adopting these schemes would require payers to take a long-term approach to decision-making – a challenging paradigm if payers are under pressure to meet short-term annual savings targets.[17]

Values Considered in HTA of Medical Technologies

NICE HTA recommendations influence payers' reimbursement decisions, so it is important for manufacturers to understand the factors that contribute to positive HTA recommendations for devices. Interestingly, both an oral presentation by Frances Nixon (NICE) and a poster by Gengshi Chen (Costello Medical) analysed factors influencing decision-making by NICE's Diagnostic Assessment Programme (DAP), including cost-effectiveness and other considerations.[18, 19] While an incremental cost-effectiveness ratio (ICER) threshold of £20,000–£30,000/QALY gained was mostly adhered to by NICE when recommending diagnostics, the committee also considers uncertainty in clinical effectiveness and non-health related factors, such as patient preferences or implications for resourcing or service provision elsewhere in the NHS.[18, 19] This indicates that, although evidence requirements for regulatory approval and reimbursement are – rightly – key areas of focus for device manufacturers, NICE does take into account the 'bigger picture' to ensure all relevant factors contribute to their decision-making.

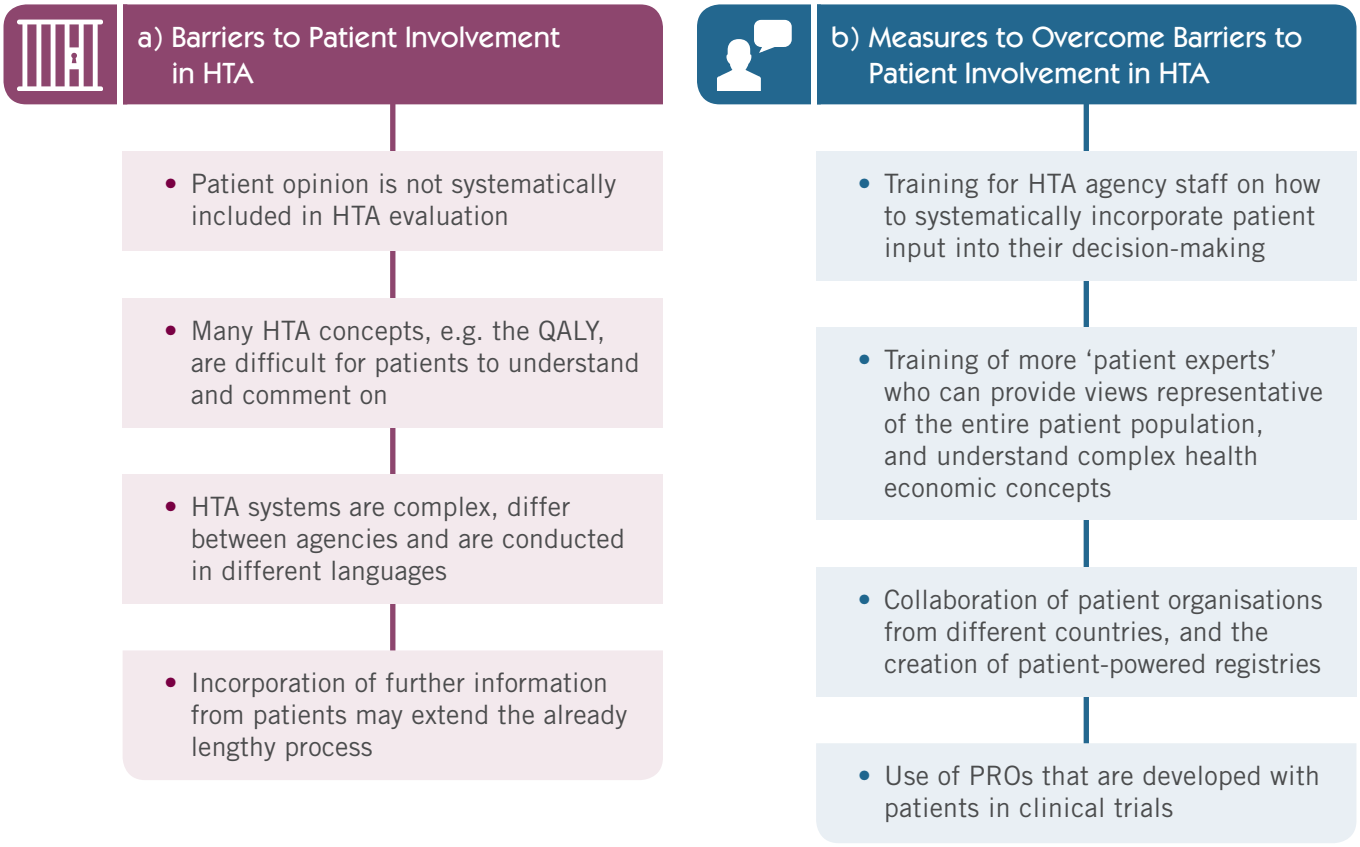
Incorporation of Patient Value in HTA

The first plenary of the congress asked, "where is the value in value-based health care?" In response, a variety of sessions throughout the congress made the case that value in health care should be defined by patients themselves. Accordingly, the incorporation of the patient perspective into HTA and the inability of generic utility measures to fully capture patient preferences were noted as key matters for discussion.

Incorporating the Patient Perspective into HTA

Patient group involvement in reimbursement evaluations is increasing, with HTA bodies worldwide gradually adjusting their infrastructure to permit the incorporation of patient opinion in healthcare reimbursement decisions. Nevertheless, in 2016 less than half of the assessments made across leading HTA bodies internationally involved patient group submissions.[20] A variety of barriers remain that prevent patient involvement in reimbursement decision-making. Issue panels comprising patient experts, HTA agency representatives, patient-reported outcome (PRO) designers and pharmaceutical manufacturers discussed these barriers, and measures that may be introduced to overcome them **(Figure 5)**.[20, 21]

Figure 5. Barriers to Patient Involvement in HTA and Measures to Overcome These Barriers[20, 21]



HTA – Health Technology Assessment; PRO – Patient-Reported Outcome; QALY – Quality Adjusted Life-Year.

Generic Utility Measures: Do They Really Capture Patient Preferences?

A number of talks at the conference noted the increasing scrutiny of the adequacy of current methods for evaluation of patients' health-related quality of life and whether they truly reflect the patient perspective. Accordingly, the validity and practicality of using generic and/or disease-specific utility instruments in HTA was discussed by representatives from the pharmaceutical and healthcare industry, HTA agencies and academia in a series of workshops and issue panels.[22-24]

Generic instruments for utility measurement, most prominently the EQ-5D, still dominate among HTA evaluations, based on the preference for a standardised and consistent approach across appraisals of medicines in different disease areas. Where generic utility measurements are not available, HTA body guidance, such as that provided by NICE,[25] generally still recommend the mapping of disease-specific values to the EQ-5D. However, this approach has been noted to combine the potentially limited content validity of the generic instrument with the low predictive power and uncertainty resulting from the application of mapping algorithms. It was therefore recommended that the development and use of disease-specific utility instruments (DSUIs) should be further incentivised.[22]

Methodological Advances in Real-World Evidence Analysis

Use of real-world evidence is often a central theme at ISPOR, and this year was no exception. Interestingly, there were many presentations on methodological approaches that can be considered when working with real-world evidence.

Disconnected Networks

The relevance of using single-arm or non-randomised studies to inform indirect comparisons was highlighted following the release of NICE guidance last year that reviewed the use of patient-level data to inform such comparisons.[26] Population-adjusted indirect comparison methods such as matching-adjusted indirect comparison (MAIC) are becoming more common in NICE single technology assessment submissions.

Evidence Review Group (ERG) feedback from these submissions has suggested that, when making unanchored comparisons, it is favourable to adjust for all potential prognostic factors and effect modifiers, even if this greatly lowers the effective sample size. It was also noted that MAIC was more widespread than the other established simulated treatment comparison (STC) method, and both methods were most frequently used in oncology. Other discussion points included the risk of generating different results depending on the target population and the need to understand bias from unobserved differences between studies.[27]

Jeroen Jansen (Precision Health Economics) and colleagues presented a workshop reviewing techniques for use in the absence of patient-level data. Aggregate level matching and reference matching can be used to generate comparative efficacy estimates using aggregate data that are disconnected from the treatment network. However, it is unclear how these methods would be received by HTA bodies and it was stated that analyses using patient-level data are usually preferred.[28]

Machine Learning and Predictive Modelling

The term "real-world" does not exclusively incorporate observational or non-randomised studies; other data sources such as claims databases and social media forums are also relevant. The use of machine learning algorithms to classify posts on several renal cell carcinoma forums was explored, with the aim of allowing determination of whether patients were experienced or naïve to treatment, and possible treatment pathways of these patients.[29] The use of similar algorithms to predict undiagnosed Hepatitis C patients, using retrospective health claims data, was also investigated.[30]

Synergy Between Real-World and Randomised Evidence

The extent to which observational evidence can complement or substitute randomised evidence was reviewed, using propensity score matching to match pre-market randomised control trial data to post-market claims data. The aim of this research was to explore and potentially predict treatment performance in a realistic setting, rather than a highly regulated clinical trial setting.[31] Although exploratory, this and similar research begin to explore how we can utilise the wealth of real-world evidence available to inform healthcare decisions.

Decision Modelling in the Evolving Therapeutic Environment

As expected at ISPOR, workshops, forums and issue panels on decision modelling techniques featured throughout the event.

Sequential Modelling

Sequential modelling explicitly considers the sequence of modelled treatments, in contrast to "line-specific" models that focus on the line of treatment under evaluation only. It was noted that sequential models are becoming more relevant in oncology as the number of alternative treatments and patients' life-expectancy increase. Furthermore, as new oncology therapies are often initially approved in a later treatment line followed by appraisal in an earlier treatment line, sequential modelling is increasingly needed to compare the same therapy in different lines of treatment. Matt Stevenson (ScHARR, University of Sheffield) presented on this topic and indicated that in his experience he would expect use of a sequential model to be appropriate where there are more than two subsequent lines of treatment following the intervention under evaluation.[32]

Partitioned Survival Analysis versus State Transition Modelling

One workshop provided a dedicated discussion on the use of partitioned survival analysis (PartSA) versus state transition modelling (STM),[33] a highly relevant topic following the publication of Technical Support Document 19 on this topic in June 2017.[34] The workshop presented an overview of the industry perspective and suggested that there is a need for the development of best practice guidelines on implementation of STM, including the use of endpoints not specified in trials (e.g. post-progression survival) and the handling of additional parametric uncertainty. In addition, Robert Hettle (AstraZeneca) predicted that HTA submission dossiers would have to increase in length and complexity as additional analyses would be required to inform the transition probabilities for STM. It was acknowledged that both industry and payers need to better understand the relative merits of PartSA versus STM in decision modelling, and that a consensus on the most appropriate modelling approach is needed to allow for consistency in future HTA appraisals.[33]

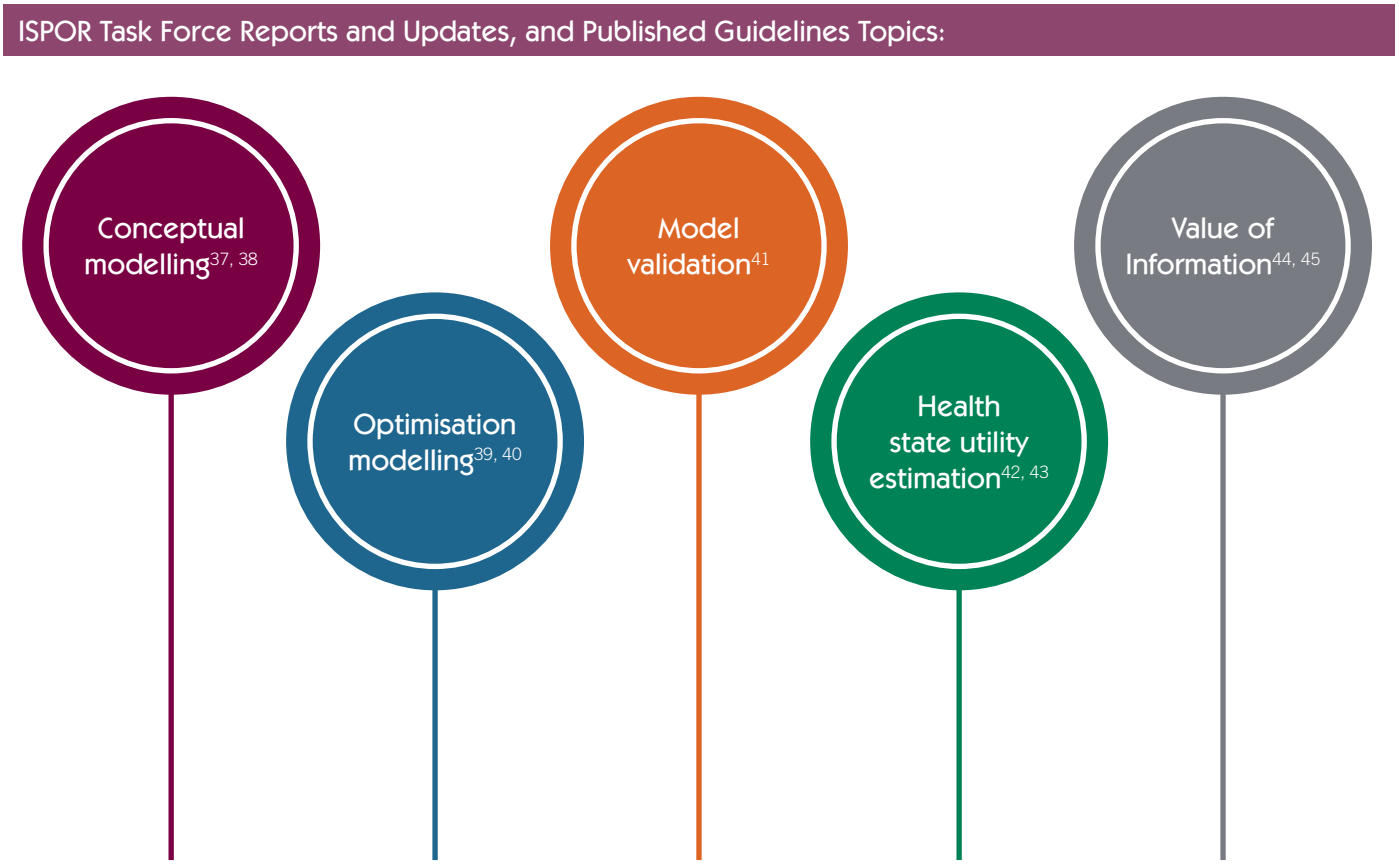
Decision Modelling for Immuno-Oncology Therapies

A number of sessions addressed the challenges facing modelling and HTA in light of the emergence of novel immuno-oncology therapies to the market. A key focus was on the statistical and clinical validity of the use of alternative extrapolation techniques when presented with a complex overall survival hazard function, for instance via spline, mixture, cure or landmark models.[35, 36] Of note, Andrew Briggs (Visiting Investigator at Memorial Sloan-Kettering Cancer Center) commented that spline and mixture models essentially represent an exercise in statistical fit, whereas cure and landmark-based models have the advantage of being grounded in belief in an underlying clinical mechanism. However, it was acknowledged that decision-makers remain reluctant to accept these newer techniques. The pharmaceutical industry was therefore issued with the challenge of providing longer follow-up data to empirically demonstrate that cure and landmark models could predict long-term survival more accurately, in order to convince decision-makers of the validity of these novel methods.

Updates to Task Force Reports and Guidelines

Finally, the conference provided the opportunity for updates on a number of task force reports and published guidelines related to health economic modelling, as outlined in **Figure 6**.

Figure 6. ISPOR Task Force Reports and Updates, and Published Guidelines Mentioned at ISPOR Glasgow



Costello Medical

Costello Medical provides scientific support to the healthcare industry in the analysis, interpretation and communication of clinical and health economic data. Due to growing demand across an increasing range of service offerings and geographies, Costello Medical has grown organically since its foundation in 2008 to a team of over 100 based in Cambridge, London and Singapore.

Alongside our evolving technical and creative capabilities, we remain committed to our core values of high quality scientific work coupled with exceptional customer service at competitive and transparent prices. Our talented team has experience with a variety of leading pharmaceutical and device companies across an extensive range of therapy areas and geographies, including Europe, Asia Pacific and North America. In addition to our provision of services broadly across the pharmaceutical industry, we also have dedicated teams with specific areas of expertise, for example medical devices and rare diseases, and can provide the full range of our services for customers specific to these areas. For more information on our services, please visit our website at www.costellomedical.com.

Further Assistance

If you would like any further information on the themes or research presented above, please do not hesitate to contact Jeanette Kusel at jeanette.kusel@costellomedical.com. Many of the presentations from the congress can be found at https://www.ispor.org/Event/ReleasedPresentations/2017Glasgow.

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20. Issue Panel IP23: How Do You Incorporate the Patient Perspective into Health Technology Assessments? Defining Best Practices for Rigorous Scientific Evidence and Impactful Submissions and Reviews. ISPOR 20th Annual European Congress, Glasgow, 2017.
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