



ISPOR 2024

May 5-8, 2024, Atlanta, GA, USA



Key takeaways



The ISPOR 2024 conference in Atlanta is themed "HEOR: A Transformative Force for Whole Health". Will this advocated, holistic approach to HEOR, which is conceptually not new, be reflected in future drug pricing?

In strategic forecasting, pricing and market access are key parameters. The Inflation Reduction Act has dominated the headlines on this topic since its introduction to the US in 2022. However, without much detail on its impact on net price being known yet, what can be learned from the initial negotiations?

No conference is without AI nowadays. What is the role of generative AI in Health HEOR and RWE? And, of course, Real World Data (RWD) and data analysis remain evergreen topics at ISPOR.

Here is groupH's pick of this year's key messages.

The benefits of a holistic approach to health are well accepted but value beyond the patient has yet to significantly and directly impact pricing and reimbursement decisions

The first plenary session, "*Are we succeeding in HEOR to advance whole health?*", emphasised the need for a multifaceted approach to HEOR, encompassing physical, behavioural, and socioeconomic factors and it explored themes like "Patient to Person," "Healthcare to Health," and "Invisible to Visible". Is the US shifting from patient-centred to a person-centred healthcare model? Yes, and No. Yes, because providers and patients acknowledge the holistic nature of health. No, because value beyond the product and the patient still struggles to be reflected directly in pricing and reimbursement negotiations.

The complexity emerging in IRA's price-setting process was highlighted as CMS prepares for another round of negotiations

As CMS gears up for a second round of negotiations, uncertainties in the initial offer price determination process remain, despite ongoing efforts to refine and improve the mechanism. While the revised draft guidance [CMS.gov](https://www.cms.gov), released on May 3, 2024, aims to incorporate lessons from past experiences there is still an ongoing debate over whether a quantitative 'cookbook' approach (every factor quantified and weighted) versus a qualitative 'blender' approach (no direct link between factors and price adjustments) should guide the initial offer price. As long as the dust has not settled, most speakers recommend to remain engaged, monitor and prepare for a process that involves both quantitative and qualitative methods in CMS's price-setting process.

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Abbreviations: AI, Artificial Intelligence; CMS, Centers for Medicare & Medicaid Services; RWD, HEOR, Health Economics and Outcomes Research; IRA, Inflation Reduction Act; ISPOR, The Professional Society for Health Economics and Outcomes Research; MFP, Maximum Fair Price; RCT, randomised controlled trial; RWD, real world data; RWE, real world evidence



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There is no information about likely future Maximum Fair Prices (MFPs) or discount levels of drugs subject to IRA. Negotiations and many factors play a role, but as a rule of thumb, groupH suggests starting with a 30% discount applied to the CMS share of patients treated from the year the IRA is likely to kick in.

More details about the process and Lessons Learned can be found here: [Lessons Learned from First 10 Drugs Selected](#).

As generative AI continues to evolve, hurdles still have to be overcome before its transformative benefits can be realised

The educational symposium, “*Advancing HEOR and RWE Research With Generative AI (GenAI)*” and the final plenary at ISPOR 2024 highlighted AI's transformative potential in healthcare. However, the benefits of AI are not materialising in all areas at the same pace. The benefits of AI analysing various health data types, including clinical care data and diagnostic imaging data, with an emphasis on automation, workflow enhancement and equity, are closer to being realised than AI is to enhancing clinical trials through predictive modelling, simulated medical scenarios and synthetic patients. The need for AI validation and bias mitigation remain known hurdles on the way to optimised treatment strategies and patient care. Ongoing education and collaboration between developers, providers and authorities are required in order to safely implement AI technologies.

Integrating diverse RWD sources to create dependable and ethical evidence demands the overcoming of challenges in data accuracy, reliability and stakeholder communication

The integration and linkage of RWD in HEOR represents a significant leap forward. This approach facilitates the synthesis of diverse data sources, such as electronic health records and patient registries, into comprehensive datasets for a comprehensive analysis. Linkage connects individual-level data from various sources using unique identifiers, forming longitudinal or cross-sectional datasets. These data enable robust observational studies, comparative effectiveness research, and cost-effectiveness analyses. While RWE complement traditional randomised controlled trials (RCTs), the second plenary session on “*Integration and linkage of RWD in HEOR*” underscored the importance of addressing these key challenges.

Experts emphasised the complexities inherent in utilising diverse data sources for decision-making. Data accuracy, reliable sources, and transparent communication and



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collaboration among stakeholders were identified as crucial for ensuring the ethical use of RWD and the generation of reliable evidence to inform effective healthcare decisions.

What we won't forget from the conference

- The IRA negotiation process and its likely outcome for manufacturers remains uncertain for now on many levels. However, for long term forecasting, a high-level, rule-of-thumb discount is needed for your forecast. groupH proposes to use an average rate of ~30% for the Medicare insured share of target patients from the year the IRA rebate might kick in onwards
- RWD and HEOR remain evergreen topics. Important but only indirectly supporting key forecast assumptions
- AI has also made its way to ISPOR. Its multitude of possible uses promise long term opportunity and transformation, but high validation and educational hurdles prevent any short term impact in market access or pricing & reimbursement
- We note the continued, holistic approach to health that ISPOR has been advocating this year was expressed by numerous sessions focused on patient-centredness in research and decision making.¹ But we also continue to watch how this approach will exactly translate to pricing negotiations in the long term

By Erik Holzinger, groupH, London and Keshalini Sabaratnam, London

¹ Patient-Centred Evidence Assessment, Patient Focused Drug Development, Patient-Centered Research, Patient Perspectives, Patient Experience Data, Patient Preference Studies, Patient Engagement, PROs