DAY 2 AT EPA

Our overview of:

the keynote and insights emerging from the global market access landscape

WORLD EPA CONGRESS
12-13 March 2024

Remap

KEYNOTE

OPTIMIZING MARKET ACCESS AND PRICING - LEVERAGING INTEGRATED EVIDENCE TO DEMONSTRATE VALUE

INTRODUCTION

In the ever-evolving landscape of healthcare and reimbursement, stakeholders such as policy makers, payers, and manufacturers face the imperative to navigate towards value-based care over volume-based models. Economic pressures in the healthcare marketplace necessitate a shift towards more cost-effective delivery of healthcare services, placing increasing strain on payers to optimise their spending. While traditional pill-based models persist, there is a growing consensus across the healthcare spectrum about the need to align drug prices with their actual value.

THE DISCUSSION

One promising solution gaining traction is the adoption of value-based contracts (VBCs), which come in several types:

Outcome-based contracts	These contracts link costs or discounts to specific patient outcomes.
Conditional treatment continuation	This involves tying continued coverage of treatment to meeting short-term treatment goals, often accompanied by a free trial period for the medication.
Indication-based pricing	Under this contract, the net price of a medicine varies depending on different indications, as agreed upon between the parties.
Expenditure cap	These agreements set a limit on the cost of medicine per patient, negotiated to a certain threshold.

The advantages of VBCs are multifaceted:

Improved patient access:	By tying costs to outcomes, VBCs incentivise efficient use of resources, potentially widening patient access.
Reduced medical costs	Aligning payment with successful outcomes can lead to overall cost savings.
Dealing with uncertainty	VBCs allow for constructive management of uncertainties regarding a drug's safety and effectiveness, especially at launch.
Alignment of price and value	They directly address the challenge of pricing drugs based on their true value, promoting fairness and sustainability in healthcare spending.
Early access	Patients may gain access to medications during the evidence-gathering phase, fostering innovation and patient-centered care.
Reduced risk	Payers mitigate financial exposure by linking payments to predefined outcomes.

Several challenges hinder widespread adoption of VBCs:

- Data availability: Insufficient data to measure value accurately remains a significant hurdle.
- Administrative complexities: Implementing VBCs requires streamlined processes and agreement on outcome measures.
- Definition of value: Stakeholders often have differing definitions of value, complicating contract negotiations.

Real-world evidence (RWE) plays a pivotal role in enabling VBCs, yet fragmented healthcare data often leads to measuring what is convenient rather than what truly matters. Early engagement with stakeholders and strategic partnerships are crucial for developing tailored VBCs that align with everyone's goals. Key factors in selecting outcome measures include credibility, relevance, practicality in data collection, comparability across settings, and adherence to legal and compliance standards.

While RWE presents challenges such as data timeliness and participation rates, it remains foundational in driving informed decision-making within VBC frameworks.

THE KEY TAKEAWAYS

1. VBCs encourage collaboration among payers, providers, patient organisations, and biopharma entities.

2. VBCs hold the promise of containing healthcare costs while enhancing patient outcomes and access.

3. Selecting the right outcome measures and utilising accurate data are fundamental to the success of VBCs.

In conclusion, the shift towards value-based contracts represents a pivotal moment in healthcare, demanding collaboration, data-driven decision-making, and a shared commitment to delivering value across the healthcare continuum.

DIGITAL TRANSFORMATION TRACK

EMPOWERING PATIENTS TO COLLECT THEIR OUTCOMES - MAKING VALUE-BASED HEALTHCARE A REALITY

INTRODUCTION

Why should we empower patients to collect their outcomes? The simple answer is: it leads to better outcomes. However, achieving this requires consensus in the care pathway between patients and providers.

Empowering patients has shown remarkable success in improving outcomes, as seen in the case of prostate cancer where utilising Patient Reported Outcome Measures (PROMs) resulted in enhanced Quality of Life (QoL). Yet, to continually improve outcomes, we must enhance clinical guidelines, optimise costs, and ensure that the entire healthcare ecosystem, from patient access to provider engagement, values and integrates Patient Reported Outcomes (PROs) effectively.

THE DISCUSSION

Currently, there are approximately 400 digital health apps, but only a small fraction are integrated with national or local care records. Within the next 5-10 years, it will become standard for these apps to seamlessly integrate with electronic health records, providing a more efficient data collection method.

While some Health Technology Assessment (HTA) bodies consider the patient perspective, future impact will come from leveraging this patient-driven data. Recognising the significance of PROMs, especially in chronic conditions that necessitate a blend of self-care and healthcare, is vital for informed decision-making in healthcare.

Healthcare has also improved significantly through the use of data-collecting devices like wearables. Allowing patients access to their healthcare data, as exemplified by the NHS app, facilitates data sharing among healthcare providers, promoting better patient-centered care. However, integrating patient-reported outcomes into HTA processes remains a challenge.

This transition will require time as we must address concerns about data quality and patient engagement. Studies indicate that patients often disengage from apps over time, highlighting the need for direct patient engagement to sustain outcomes reporting. Additionally, ensuring the credibility of patient data presented to payers and HTA bodies is crucial, possibly utilising generative AI and machine learning for data analysis.

PROs offer external validity that clinical trials alone cannot provide, offering personalised insights that enrich QoL assessments. Combining clinical data with PROs is essential for achieving optimal patient outcomes.

THE KEY TAKEAWAYS

1. Understanding high-quality data is crucial; currently, only 3% of hospital data is utilised. Patient engagement also suffers when data requirements are overwhelming, leading to discontinuation of outcomes reporting.

2. PROMs are invaluable but require better integration with HTA processes. HTA bodies must recognise the pivotal role of PROs in decision-making.

3. Prioritising patient outcomes before access decisions leads to the most significant successes in healthcare interventions.

By empowering patients and integrating their perspectives into healthcare decision-making processes, we pave the way for more effective and patient-centric healthcare systems globally.

NICE ENOUGH? DO NICE DECISION OUTCOMES IMPACT INTERNATIONAL HTA DECISION-MAKING

INTRODUCTION

The influence of decisions made by the National Institute for Health and Care Excellence (NICE) in the United Kingdom on healthcare systems worldwide remains a topic of ongoing investigation. Despite limited direct evidence of NICE decisions impacting other countries, a recent study delved into this complex issue. This study encompassed 12 countries, encompassing both developing and well-established Healthcare Technology Assessment (HTA) systems. Employing a mixed-methods strategy, it utilised quantitative techniques to examine inter-agency links and qualitative methods to uncover potential factors of NICE processes that might resonate with other agencies globally.

THE DISCUSSION

Three correlations were identified:

1. NICE positive decisions correlated with positive outcomes elsewhere
2. NICE optimised decisions often related to negative outcomes in other countries
3. NICE terminated or negative decisions are often associated with no HTA appraisal in other countries.

There is a suggestion (though not statistically significant) that the level of consensus on decision outcomes between NICE and the relevant HTA agency was greater in Poland, Italy, South Korea, and Sweden.

Considerations

- Further research on how to increase the efficiency of HTA processes is needed, assessing whether it should come from collaborative efforts, joint assessments and/or adaptation of evidence generated in or for other geographical.
- The transferability of HTA decisions between jurisdictions is limited due to varying parameters like costs, contextual factors and health systems characteristics.
- Decision makers are more likely to look at NICE documentation for more complex appraisals such as innovative therapies or high cost products
- Negative NICE decisions are likely to have more impact internationally compared to positive one's.
- Influence stems from underlying factors, such as the perception of NICE as a methods innovator and the accessibility of NICE's outputs.
- Collaboration between HTA agencies, particularly those using cost-effectiveness analysis, might strengthen NICE's role on the international stage.

THE KEY TAKEAWAYS

1. NICE has some impact on HTA decision making in other countries, but the means and extend vary considerably and are less driven by the outcomes of individual appraisals. In other words, HTA decisions don't necessarily travel but decision-making evidence does.

2. NICE is not part of the new EU HTA regulation including Joint Clinical Assessment. This and other post-Brexit activities could weaken NICE's influence in the EU region. This potential lack of involvement may weaken NICE's ability to shape health policies and practices in the EU, impacting its influence on healthcare decisions and potentially hindering the adoption of its guidelines and recommendations across member states.

3. NICE may have more resources available compared to newer or less developed HTA bodies. Based off the interviews conducted, they found that HTA bodies with fewer resources or less experience might look to NICE's interpretation and critique of company evidence to help their own critique of the submitted evidence.

MARKET ACCESS TRACK

THREE WAYS ARTIFICIAL INTELLIGENCE (AI) WILL IMPACT MARKET ACCESS IN 2024

INTRODUCTION

Artificial Intelligence (AI) is increasingly revolutionising the pharmaceutical industry especially in clinical development and commercialisation strategies, yet its integration into market access strategies remains a work in progress. Key uses of AI to support market access were highlighted, including helping to inform price predictions and country sequencing strategy during product launches. The optimal use of AI in market access strategies is dependent on the disease landscape in which the company is launching.

LEVERAGING NATURAL LANGUAGE MODELS FOR COMPETITIVE LANDSCAPE ANALYSIS

In the scenario where the landscape is competitive, natural language models to analyse previous HTA reports of competitor products may be a useful tool to help predict HTA outcomes for a new product. These models can help to inform companies on previous decisions for comparator products and allow direct queries to be answered on payer opinions regarding the trial design, duration, size, endpoints chosen and outcomes. The outputs of these analyses can help to inform the market access strategy to mitigate any potential challenges when launching and to effectively differentiate the value of the new product versus the competitor.

MACHINE LEARNING MODELS FOR PRICE PREDICTION IN COMPLEX SCENARIOS

In scenarios lacking clear comparators, machine learning models trained on extensive pricing and market access datasets become instrumental in price prediction.

These models delve into potential price drivers such as disease severity, unmet need, budget impact, and target population characteristics. While offering valuable insights in uncertain areas, it's important to note that the accuracy of data generated by machine learning models from large datasets may be slightly lower compared to the targeted approach typically used in HTA analyses.

AI'S STRATEGIC ROLE IN COUNTRY SEQUENCING AND PRICING STRATEGIES

Beyond price prediction, discussions revolve around AI's potential in informing country sequencing strategies during product launches. Modelling international reference pricing dynamics allows for optimised country launch sequencing, with adjustments tailored to factors like country-specific reimbursement timelines, commercial demands, and internal launch preparedness. This strategic utilisation of AI not only navigates complex international markets but also maximises market access potential, ensuring efficient and successful product launches across diverse global territories.

IN CONCLUSION

Overall, AI can be an invaluable asset to inform the market access strategy for pharmaceutical companies. However, its value is dependent on the quality of data that are inputted into the relevant models that subsequently determines the accuracy of the insights provided by AI. Market access teams also need to have the data sciences expertise with sufficient market access knowledge to understand how the AI models should be applied to provide relevant outputs.

As companies begin to apply AI, it is important that all stakeholders understand the limitations in the accuracy of the data generated by each model type and continue to use individuals' expertise to sense check the outputs provided and their applicability to specific products. If used appropriately, AI may be a valuable tool for developing market access strategies at a faster rate with a lower burden on team resources.

We always welcome your thoughts and opinions on the topics raised at EPA.

If you'd like to share anything from your Amsterdam experience or hear how we can support you in getting your product to market, email our leadership team today at contact@remapconsulting.com or reach out personally by clicking their email below.

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