

Designing evidence for the journey, not just the milestone

AI is making evidence faster to produce. JCA is making parts of it easier to share. Real-world data is making it possible to learn more from what happens after a technology reaches clinical practice.

And yet, none of these developments changes the fundamental challenge facing HEOR: **evidence only creates value if it reaches the decision it was designed to support.**

That has been the underlying question behind the articles I have written before this one. I started with what happens to the HEOR professional when AI can increasingly perform parts of the analytical work. I then questioned whether HEOR can really become generic when markets, disease definitions and patient populations continue to evolve. Most recently, I looked at what happens when we have generated the right evidence but still need to translate it into a decision and ultimately into patient access.

Looking across those questions, I increasingly believe that we have been thinking about evidence in the wrong shape. We tend to build an evidence package around a milestone, when we should be designing evidence around a journey.

This is something I have experienced repeatedly across Pharma and MedTech. A submission naturally creates a clear endpoint: a regulatory decision, an HTA assessment, a reimbursement decision or a launch. We define the question, generate the evidence, build the model and assemble the package. But healthcare does not stop moving when the submission is made. Clinical practice changes, new comparators emerge, treatment pathways evolve, patient populations become better understood and new evidence changes what we thought we knew. Sometimes the most important change is that the question itself has changed.

One of the clearest examples I have experienced was obesity. Working with Wegovy, the challenge was not simply to generate evidence for a new treatment. It was also about understanding and helping shape a changing category around how obesity was perceived, treated and valued. Obesity had long been framed largely through a lifestyle lens, whereas the conversation increasingly moved towards recognizing it as a chronic disease requiring long-term medical management. That is a very different starting point for a healthcare system.

The task therefore became much bigger than demonstrating the efficacy of a medicine. It meant understanding who the relevant patient was, what constituted unmet need, where pharmacological treatment belonged in the care pathway, how long-term treatment should be considered, and what value meant in a healthcare system that was itself having to reconsider the disease. That required extensive market insight, stakeholder engagement, market research, clinical understanding and evidence generation. The evidence had to help explain not only whether the treatment worked, but what the changing disease landscape meant for patients, healthcare professionals and the system around them.

What made this particularly challenging was the speed and scale of the change. The market was not simply moving from one product category to another; the category itself was being redefined. NICE's subsequent work in obesity illustrates how complex this becomes when long-term treatment effects, discontinuation, comorbidities, care pathways and resource implications all become part of the evidence question. [NICE – Disease-specific reference case extension: management of overweight and obesity in adults](#)

That experience changed the way I think about evidence. The challenge is not always to generate better evidence for an existing market. Sometimes the market itself is changing so quickly that the evidence strategy must help explain what the new market should look like. And once that happens, the evidence journey becomes inseparable from the healthcare system in which the technology is being introduced.

The US healthcare system illustrates this in a different way. Regulatory authorization, coding, coverage and payment involve different decision-makers and different questions. FDA's work on payer communication recognizes that evidence relevant to regulatory decision-making may not be sufficient for subsequent coverage decisions, while CMS's Coverage with Evidence Development demonstrates how coverage and further evidence generation can be connected. The 2026 RAPID pathway from FDA and CMS takes this thinking further by bringing regulatory and coverage considerations closer together for certain medical devices. [FDA – Medical Device Coverage Initiatives](#) · [CMS – Coverage with Evidence Development](#) · [FDA/CMS – RAPID Coverage Pathway](#)

For me, the important lesson is not about the US system itself. It is that evidence does not move through healthcare in a straight line. The question changes as a technology moves from one decision to another, and therefore the evidence strategy must be able to move with it.

This becomes particularly relevant as Europe moves towards greater cooperation through the Joint Clinical Assessment. JCA creates an opportunity to reduce duplication and make parts of the clinical evidence base more transferable across countries. I believe this will increasingly influence how global evidence strategies are designed. If parts of the clinical assessment can be reused across markets, there is considerable value in thinking about transferability much earlier rather than adapting evidence retrospectively for each country.

But there is an important distinction: **evidence may become increasingly portable. Value remains contextual.**

The EU HTA framework supports joint clinical assessment while leaving pricing and reimbursement decisions at national level. [European Commission – Health Technology Assessment](#) The clinical evidence may travel more easily; the interpretation of that evidence still depends on the healthcare system in which the decision is made.

This is also why I do not think JCA will make national HEOR disappear. If anything, it may make the contextual part of HEOR more important. NICE, TLV and other national HTA bodies may work from broadly similar principles, but they operate within different healthcare architectures, decision rights, funding mechanisms and clinical pathways. The evidence may be shared; the decision environment is not.

NICE is a good illustration of why context matters. Its health technology evaluation methodology considers not only clinical evidence, but the decision problem, population, comparator, clinical and patient experience, uncertainty, the position of the technology in the care pathway and whether the economic model reflects the decision being made. Implementation and changes in clinical practice can also matter. [NICE – Health technology evaluations: the manual](#)

A sophisticated analysis can therefore still be the wrong analysis if it does not answer the question that matters to the decision-maker.

This is perhaps where my own thinking has changed most over the years. Earlier in my career, I naturally thought a lot about whether we had generated the right evidence for the submission in front of us. With experience across different markets and both Pharma and MedTech, I have become increasingly interested in **what happens when the context itself starts to move**. What will the next decision-maker need to know? Which assumptions are likely to change? What happens if clinical practice evolves? And what evidence

could we generate after launch that would allow us to understand whether the assumptions behind the original value story still hold?

The answer is also shaped by how a healthcare system actually makes and funds decisions. A technology entering a relatively centralized system with national or regional budget responsibility faces a different value conversation from one entering a more fragmented payer environment. The same is true when responsibility for funding sits at different levels of the healthcare system, or when patients themselves carry a larger share of the cost. The relevant question is not simply whether a technology is cost-effective. It is where the economic consequences land, who carries the uncertainty, who has the authority to act on the evidence, and how quickly a decision can change when new evidence emerges.

This is one reason why I think global evidence strategies need to become more sophisticated about the difference between evidence that can be standardized and context that cannot. The temptation is to treat markets as variations of the same problem. In reality, the institutional architecture can fundamentally change what evidence matters and how that evidence is used.

Sweden's approach through TLV is interesting in this context. TLV's work on following drug utilisation and treatment effects in clinical practice illustrates how evidence can continue to matter after an initial reimbursement decision, particularly where uncertainty remains. [TLV – Follow-up of drug utilisation and treatment effects in clinical practice](#)

Denmark offers another perspective. Our national health data infrastructure creates significant opportunities to understand treatment and outcomes over time, and Healthcare Denmark highlights health data as one of the country's important strengths. [Healthcare Denmark – Collection and sharing of health data](#) The opportunity is therefore not simply to generate more real-world evidence, but to make evidence generation more continuous.

And this brings me back to AI.

When I wrote my first article, I asked what HEOR professionals should become exceptionally good at if AI can increasingly do the analysis. I still believe the answer involves judgement, context and the ability to challenge assumptions. But after working through the themes in these four articles, I think there is something more fundamental: **we need to become better at designing evidence as an evolving system rather than treating it as a finished deliverable.**

AI will make it easier to search, synthesise, structure and analyse information. ISPOR's 2026–2027 Top 10 HEOR Trends, where AI ranks first and RWE second, reflects how quickly this is becoming reality. [ISPOR – 2026–2027 Top 10 HEOR Trends](#)

But the easier evidence becomes to produce, the more important it becomes to know what evidence is actually worth producing. Otherwise, we risk creating a highly efficient system for answering questions that no longer matter.

That is why I increasingly see the future of HEOR not as a choice between generic and bespoke, manual and AI-enabled, or global and local. **It is about understanding what can be standardized, what needs to remain contextual, and how the evidence needs to evolve as the decision environment changes.**

The submission is still important. The HTA decision is still important. The reimbursement decision is still important. **But they are milestones, not the destination.**

The real objective is to create evidence that can support decisions throughout the journey: evidence that can travel where it should, adapt when the context changes, and continue to generate learning once a technology reaches clinical practice.

For me, that is ultimately the shift we are seeing across HEOR, HTA, RWE and AI. We are moving from an environment where evidence is something we build for a decision, towards one where evidence needs to remain connected to the decision throughout its lifecycle.

And perhaps that is the role of the HEOR professional I have been trying to define through this series. Not simply the person who can produce the most sophisticated analysis, but the person who understands what evidence needs to exist, why it matters, how it will be used, and when the question itself needs to change.

Because evidence is not the strategy. **The strategy is understanding the journey.**

#HEOR #MarketAccess #HTA #JCA #RWE #EvidenceGeneration #HealthEconomics #AIinHealthcare
#PatientAccess