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VALUE & OUTCOMES SPOTLIGHT

A magazine for the global HEOR community.

HEOR & THE FUTURE OF WORK

ISPOR
Improving healthcare decisions

VALUE & OUTCOMES
SPOTLIGHT

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The mission of *Value & Outcomes Spotlight* is to foster dialogue within the global health economics and outcomes research (HEOR) community by reviewing the impact of HEOR methodologies on health policy and healthcare delivery to ultimately improve decision making for health globally.

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FROM THE EDITOR

What Is the Future of Work?

The way we work has been ever evolving—driven by advancements in technology and changes in economics, culture, and society. Until recently, changes in ways of working and productivity increases had been driven mostly by technological advances (particularly industrialization and automation) and had mostly affected the labor or "blue collar" workforce. The societal and economic impacts of these advances on that workforce have been tremendous and have forced those workers to seek other career opportunities. Although many technical and service industries still require a modern-day labor workforce, employers have clearly shifted their needs toward a more professional workforce of employees who can drive creativity and innovation within an organization. However, due to the COVID-19 pandemic, that evolution became a revolution as both workers and employers were forced to dramatically adapt their ways of working. This revolution led to a conspicuous cultural shift in the way in which work and the workplace are defined as both employers and employees began reconsidering their business models and career needs.

One outcome of this workplace revolution was the emergence of the hybrid work environment. The pandemic accelerated the normalization of the hybrid work environment, which has shown to be effective, yield cost savings, and be desirable by employees. Professionals want more independence and flexibility in how, when, and where they work. They want to be able to work from anywhere and at any time using their own devices. They want to rely on collaboration technologies and focus on deliverables and outputs (rather than inputs) and they want the flexibility to define and choose their own career paths. Arguments have been made that in-person work is still key to both business and employee success. Face-to-face interactions can boost morale, build networks, and encourage spontaneous collaboration. Regardless, employers find themselves adapting to the needs of the changing workforce to enable recruitment and retain top talent. To attract this talent, employers need to demonstrate the true value proposition of their business and define the employee experience to potential candidates. This means establishing, articulating, and living their corporate culture, leadership style, sense of purpose, and societal impact—in short, creating an organization where employees want to be there rather than need to be there. These are just some examples of how businesses can create a forward-looking corporate environment and one in which an organization can continuously evolve by understanding employees' needs. Employers are wagering that this strategy will allow them to recruit and retain the most talented professionals and will be a recipe for their future success.

Although the current revolution in the ways of working is mostly a cultural one, the next revolution may possibly be technological. As industrialization and automation have historically impacted the workforce, so may the artificial intelligence (AI) revolution impact the modern workforce, as technological advances such as ChatGPT are poised to eliminate mundane and repetitive tasks that were once thought to be performed only by humans. Industries such as

accounting, banking, finance, and even human resources have been utilizing and will continue to develop AI for their business needs. As employers look to AI to maximize efficiency, eliminate decision-making bias, and increase productivity, they will also look for employees who can work alongside AI and effectively leverage this technology and require employees to develop these relevant skills. Moving forward, the key question for businesses is how to best integrate the emerging AI technologies within the current work environment to continue to foster an innovative and productive one for both employees and employer. Given the historical example of automation and the labor workforce, employers need to be mindful that this integration may prove challenging and have significant cultural and societal impacts on the workforce.

The ways we work are constantly changing alongside changes in our culture, economy, and technology. Both employers and employees who recognize and embrace this changing environment will be able to leverage it to drive efficiency, creativity, and innovation. By creating a workplace where employees can feel empowered and engaged while leveraging technology to eliminate the mundane and repetitive tasks, employers and employees working together can create a workplace environment where both can thrive and be successful. Doing so can increase productivity, inspire creativity, drive innovation, and foster connectivity to create a brighter future of work for all.

As always, I welcome input from our readers. Please feel free to email me at zeba.m.khan@hotmail.com.

Zeba M. Khan, RPh, PhD
Editor-in-Chief, *Value & Outcomes Spotlight*

ISPOR SPEAKS

Seeing ISPOR—and HEOR—With New Eyes

Rob Abbott, ISPOR CEO and Executive Director

The French novelist, Marcel Proust, famously said "the real voyage of discovery consists, not in seeking new landscapes, but in having new eyes." I've been thinking about this a good deal since taking the helm of ISPOR on March 13, 2023. I feel very fortunate indeed to have inherited an organization of uncommon strength—in products, services, and especially, in people. The Board, the staff, and the members are so passionate about our vision and mission, and equally, so caring of one another. A good deal of credit here must be paid to my predecessor, Nancy Berg, who guided ISPOR for 8 years and was sensitive to the visible and less visible practices that can come together to create something special. This work, and the foundation of trust that it represents, now gives us *opportunity*. An opportunity to see ISPOR's role in the world with new eyes. Let me explain.

The COVID-19 pandemic overturned many assumptions about how we live, work, and play together. Public health measures such as wearing face masks, working remotely, carrying a vaccine "passport" or QR code, social distancing, and avoiding indoor gatherings became ingrained in the culture. The word "hybrid" is now commonly used to denote a combination of in-person *and* virtual engagement with life. At the same time, the healthcare landscape has changed. Some of this was motivated, or at least accelerated, by the pandemic, but much of it was well underway prior to 2020 and simply expressed itself in a more obvious way in the past 3 years. The digital health transformation is perhaps the most extravagant example of change in this regard. It is now widely accepted that digital capabilities are fundamentally important to health systems seeking to prioritize convenience and access to care for patients. It should also be acknowledged that health systems in many parts of the world were facing significant structural challenges prepandemic, including underfunded primary and social care, workforce shortages, and inequities in access to care.

ISPOR, as the leading professional society in health economics and outcomes research (HEOR), has been attuned to many of these changes and has taken steps to ensure that we are not simply tracking the major trends that affect healthcare decision making, but that we are also actively engaged in *shaping* the conversation about these trends. A good example is our work on real-world evidence (RWE). It is well-known that RWE can offer large sample sizes that enable analysis of subpopulations and less-common effects, and equally, that it can provide a representation of real-world practice and behaviors—all of which are difficult to achieve with randomized clinical trials. What is less well-known, and what is increasingly driving ISPOR's thought and action in RWE, is a fuller articulation of the many ways in which it might be expressed—in regulatory decision making, in medical device assessment, in patient-centered RWE, and so on. It is also important to us to understand the relationships between RWE and real-world data (RWD). And so it is that we are exploring causal inference in RWD, genomic RWD, and so on. These are not simply esoteric or academic diversions; this work lies at the heart of our efforts to better understand innovative approaches to evidence generation; causal inference; the application of machine learning and artificial intelligence to patient care; the role of RWE in digital health delivery; and many other aspects of healthcare that lead to better outcomes for patients and healthcare providers.

The RWE example that I've just discussed is reflective of the tremendous opportunity I see for ISPOR to "raise the height of its radar" and become more centrally involved in discussions about the path healthcare is traveling through time and how a more deeply embedded commitment to HEOR can improve healthcare decisions globally. This is akin to "having new eyes" for HEOR. To those who are entrenched in HEOR work, its value is—and is seen to be—a given. I want to ensure that ISPOR continues to stay close to this core constituency while simultaneously growing its reach. We will continue to define best research practices in the science of HEOR and promote its use to improve healthcare decision making globally. This will require us to accelerate stakeholder engagement, broaden our member involvement efforts, and double down on our efforts to communicate the impact—*the value*—of HEOR in research and decision making.

The complexity of healthcare decision making continues to intensify across the globe. Innovative treatments based on precision or personalized medicine are no longer a distant thing on the horizon; they are here now. However, such novel therapies do not fit easily into traditional value assessment frameworks and processes—and therefore the healthcare budget-planning process. This is where ISPOR and HEOR have much to contribute. As a community we need to reach beyond our core membership and show healthcare decision makers and decision shapers across the globe that HEOR provides a framework that can both clearly define the issue at hand (eg, drug pricing, device assessment, and so on) *and* generate and assemble the *relevant* evidence to inform and guide decisions in this rapidly evolving space.

As your new CEO, I bring "new eyes" to this important topic and look forward to working with you to further grow ISPOR's profile and impact.

ISPOR NEWS

Incorporating Different Elements of Value Into Technology Assessment

Kelly Lenahan, MPH, ISPOR, Lawrenceville, NJ, USA and **Brian O'Rourke, PharmD**, ISPOR President-Elect, and Independent Healthcare Advisor, Ottawa, ON, Canada

Kelly Lenahan, MPH

Brian O'Rourke, PharmD

There is a growing emphasis for payers and health technology assessment (HTA) bodies to incorporate "novel" elements of value when undertaking an assessment of pharmaceuticals and other health technologies. Recognizing the need for education and collaboration, ISPOR introduced a strategy to increase engagement with payers in 2019. Since then, ISPOR has leveraged its unique position and world-renowned reputation to promote the use of health economics and outcomes research that informs healthcare policies and decisions. For example, an ISPOR Speaks column[1] published in 2020 in *Value & Outcomes Spotlight* highlighted ISPOR's initial efforts to engage payers. In 2020, ISPOR launched its first annual Payer Summit to allow for a more intimate dialogue between payers and industry stakeholders[2,3] and that tradition continues today.

In fact, examining the novel elements of value in assessing health technologies was the focus of the 2022 ISPOR Payer Summit, which was held virtually on September 15, 2022. Attendees of this summit represented multistakeholder perspectives from European and North American payer organizations, HTA bodies, patient groups, and industry stakeholders from the ISPOR Institutional Council.

> ISPOR has leveraged its unique position and world-renowned reputation to promote the use of health economics and outcomes research that informs healthcare policies and decisions.

The 2022 summit presented 3 different perspectives on expanding the concept of value for high-cost innovations: (1) **alternative concepts of value** (presented by Peter Neumann, ScD, Tufts Medical Center, Boston, MA, USA); (2) **what does value mean to a patient** (presented by Alan Balch, PhD, Patient Advocate Foundation and National Patient Advocate Foundation, Washington, DC, USA); and (3) **what does value mean to a payer** (presented by Iga Lipska, MD, PhD, MPH, Medical University of Gdańsk, Gdańsk, Poland).

After the panel discussion, participants were divided into 3 groups to discuss different topics: (1) avoided versus avoidable costs; (2) incorporating patient-centered research and endpoints into value assessment; and (3) how to incorporate broader societal value into clinical and economic assessments. Participants were equally divided based on their stakeholder relationship, geography, and gender.

The group that focused on avoided versus avoidable costs discussed how different countries such as Germany, Belgium, and the United States assess a product and whether they include costs when determining the value of a product. A part of the discussion also focused on how to appropriately measure health system costs. Ultimately, all parties involved in the breakout group agreed that they are trying to minimize uncertainty and maximize value. The main action point that arose from the discussion is the need to better differentiate avoidable costs from costs that are avoided, perhaps by learning how other sectors, such as manufacturing, have defined and measured these costs.

The second group focused on how to better incorporate patient-centered research and patient-important outcomes into payer-based value assessments. A case study involving patients with multiple sclerosis was presented by a representative from a European HTA body. They determined that patients want disease-modifying therapies throughout their life and do not want to stop therapy as a milestone for disability status; however, when patient preference information was input into their cost-effectiveness analysis, the model showed that patients should be taking a lower-priced disease-modifying therapy based on their disability status. They also found that when community preference data were input into the cost-effectiveness model for multiple sclerosis, the model prefers the community preferences instead of individual patient preferences. A payer from the United States discussed how they conducted a Delphi panel of patients with multiple sclerosis and found that the patients were much more concerned about slowing disability and keeping activities of daily living instead of the predicted outcomes of wanting to avoid adverse effects of medications. These examples demonstrate the importance of incorporating patient preferences into payer decision making. Some payers in the United States that are very interested in using Patient-Reported Outcomes Measurement Information System (PROMIS) data, especially with their outcomes-based contracts; international payers were not aware of PROMIS data. Low- and middle-income countries in Europe have found that it is difficult to explain the value of a product to patients, especially when describing the budget impact. They have found that patients care much more about ease of treatments instead of costs. Ultimately, all stakeholders in group 2 agreed that they should be engaging patients earlier in the decision-making process.

The final breakout group focused on how to incorporate broader societal values into clinical and economic assessments. An emphasis was made on remembering that HTA is much more than an economic assessment of the value of a technology—clinical assessments are just as important to the HTA process and while the ISPOR Value Flower is a good starting point, many feel that it focuses too much on the economic assessments of value and not clinical outcomes. All payers and HTA bodies in this group were unsure if the novel elements of value defined by the Value Flower could even fully be included into the assessment process.

HTA is much more than an economic assessment of the value of a technology–clinical assessments are just as important to the HTA process and while the ISPOR Value Flower is a good starting point, many feel that it focuses too much on the economic assessments of value and not clinical outcomes.

Some important influences on payers in the United States when making a decision include input and policies from employer groups, patient and caregiver engagement, and reports from the Institute for Clinical and Economic Review (ICER), especially their cost-utility analyses. It was questioned if patients and caregivers should be considered as 2 distinct stakeholder groups, since the caregiver perspective might be overlooked in areas where the caregiver burden is very important, such as for Alzheimer's disease.

The next ISPOR Payer Summit will take place on May 7, 2023 at ISPOR 2023 in Boston, MA, USA. For more information on the ISPOR Payer Summit or if you would like to inquire about future participation in 2024, please contact HTACouncil@ispor.org.

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1. Naaman N. Dialogue with decision makers: collaborating with payers to advance health economics and outcomes research. *Value & Outcomes Spotlight*. 2020. 6(2):7.

2. O'Rourke B, Cabra HA, Orsini LS, Guerino J. Quality, access, and the use of real-world data by payers: where are we now? where do we want to be in the future? *Value & Outcomes Spotlight*. 2021. 7(2):11-13.

3. O'Rourke B, Trusheim M, Cabra HA. Benefits and challenges of performance-based managed entry agreements: report from an ISPOR Payer Summit. *Value & Outcomes Spotlight*. 2022. 8(2):13-15.

HEOR NEWS

1 How Does the Affordable Housing Crisis Impact Health Outcomes? (Patient Engagement HIT)

A study published in JAMA Network Open, highlighting data from UCLA David Geffen School of Medicine, found that housing instability due to rent increases leads to more psychological distress, higher likelihood for emergency department visits, and lower likelihood of having preventive care visits.
Read more

2 NICE Recommended Weight-Loss Drug to Be Made Available in Specialist NHS Services (NICE)

Patients in the United Kingdom who are eligible for weight management services will have access to Novo Nordisk's Wegovy (semaglutide), after the launch of the drug is confirmed by the manufacturer.
Read more

3 A National Hepatitis C Elimination Program in the United States: A Historic Opportunity (JAMA Network)

Despite the availability of direct-acting antivirals that can cure hepatitis C in more than 95% of patients, a significant fraction of the more than 2.4 million US residents chronically infected do not receive them, with 15,000 dying each year. The Biden-Harris administration is calling on Congress to accept a 5-year program to eliminate hepatitis C in the United States.
Read more

4 Even Oncologists Sold on Value-Based Care Hesitate to Embrace the EOM (AJMC)

At a panel discussion at the Association of Community Cancer Centers (ACCC) 2023 Annual Meeting and Cancer Center Business Summit that included members of the ACCC Alternative Payment Coalition, oncologists who said they had learned a lot from Centers for Medicare & Medicaid Services' Oncology Care Model are expressing hesitation about the upcoming Enhancing Oncology Model (EOM), which only covers 7 cancer types.
Read more

5 Integrating the US Public Health and Medical Care Systems to Improve Health Crisis Response (Health Affairs)

Because of what researchers call the "operational cleavage" between the US public health and medical systems, the 3 fundamental elements of epidemic response during the COVID-19 pandemic—case finding, mitigating transmission, and treatment—were undermined by the lack of coordination between public health and medical care and contributed to health disparities. The writers suggest 3 ways—establishing a case-finding diagnostic system, data systems, and a treatment pathway—to bring these systems together.
Read more

6 Effects of Time-Restricted Eating on Nonalcoholic Fatty Liver Disease (JAMA Network Open)

A study in China of 88 adults with obesity and nonalcoholic fatty liver disease (NAFLD) found that time-restricted eating, an intermittent fasting regimen, did not produce additional benefits for reducing IHTG (intrahepatic triglyceride) content, body fat, and metabolic risk factors compared with daily calorie restriction. Researchers say these findings support the importance of caloric intake restriction when using time-restricted eating to manage NAFLD.
Read more

7 GPEI Statement on cVDPV2 Detections in Burundi and Democratic Republic of the Congo (Global Eradication Initiative)

Burundi and the Democratic Republic of Congo have reported cases of circulating vaccine-derived poliovirus type 2 (cVDPV2) linked with the novel oral polio vaccine type 2 (nOPV2), with viruses isolated from stool samples of 7 children with acute flaccid paralysis in the 2 countries.
Read more

8 Exploring the Influence of TikTok on Health Information (Duke University School of Medicine)

Duke researchers have found that top TikTok videos tend to portray negative patient experiences with intrauterine devices and provide reliable and useful information about abortion access.
Read more

9 Babies Should Be Given Peanut Products Between 4 and 6 Months to Reduce Allergy, Say Researchers (BMJ)

Because the incidence of peanut allergy has tripled in recent decades and now affects around 2% of the UK's children, researchers say the government should revamp weaning guidelines to recommend introducing peanut products to infants during a "window of opportunity."
Read more

10 Male Footballers Are 50% More Likely to Develop Neurodegenerative Disease, Finds Swedish Study (BMJ)

A study of men who played in Sweden's top division from 1924 to 2019 found that football players had a 1.6% higher risk of developing Alzheimer's disease and other dementias than the controls, with 8% of the footballers and 5% of controls in the study receiving these diagnoses.
Read more

FROM THE JOURNALS

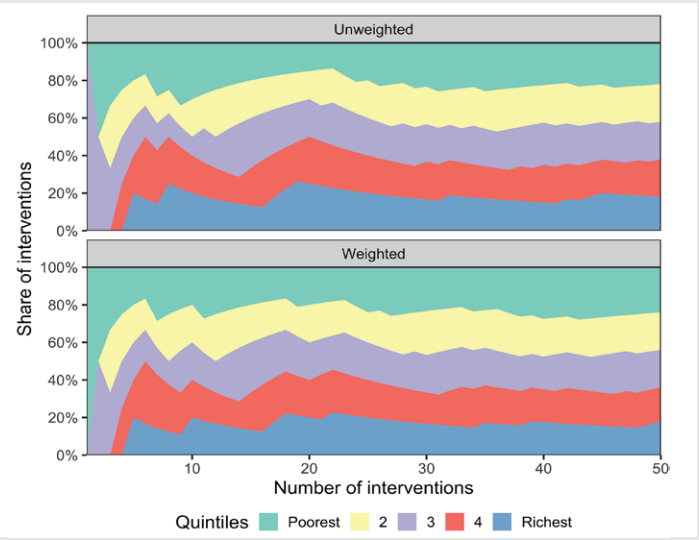
Equitable Prioritization of Health Interventions by Incorporating Financial Risk Protection Weights Into Economic Evaluations

Hendrix N, Bolongaita S, Villano D, Memirie S, Tolla M, Verguet S. *Value Health*. 2023;26(3):411-417.
Section Editor: **Agnes Benedict**; Guest Section Editor: **Sugam Mahajan**

There have been growing concerns about the need to design health policies and decision-making processes that address health equity (ie, who gains and who loses from public health programs). Given a fixed health-expenditure budget, a decision to reimburse a drug for treatment of a disease implies that funds are being diverted from treatments of another disease. Conventional cost-effectiveness analysis (CEA) used around the globe to help decision making rarely informs equity considerations. Frameworks like multicriteria decision analysis, distributional CEA, equity-weighted quality-adjusted life-years, and extended CEA have been developed that can be used by policy makers to ensure equity in distribution of health benefits. However, most of these methods are quite complex and rigorous, as they rely on a social welfare function that is reflective of society's preferences on inequality that can be difficult to estimate and to comprehend.

Addressing health equity becomes quite relevant in low- and middle-income countries where there is a high incidence of out-of-pocket expenditure on health services, affecting an individual's ability to seek timely healthcare and be able to afford it. In this context, it becomes important for the policy makers to ensure prevention of medical impoverishment by providing financial risk protection (FRP) to reduce individuals' risk of excessive out-of-pocket spending on health services via publicly financed health benefits. The authors of this paper published last month in *Value in Health* set out to develop an analytical framework for incorporating financial risk protection into priority setting for health interventions.

Figure 3. Proportion of interventions assigned to each income quintile based on rankings of unweighted and weighted deaths averted, as interventions are being selected (according to a decreasing cost-effectiveness) into a publicly financed package of interventions.



The authors identified extended CEA studies reporting health outcomes, costs, and at least one FRP outcome for an intervention (ranging from vaccines, neonatal home care, strengthening surgical units, malaria prevention, among others), with the majority of studies from Ethiopia and India. The common FRP measure was "out-of-pocket expenditures averted" that was converted into "income-adjusted out-of-pocket averted" by dividing the out-of-pocket expenditure averted by quintile-specific per capita income estimates based on a World Bank Database.

In total, 31 interventions were assessed, including 29 cases reporting out-of-pocket expenditure averted as an FRP metric. FRP weights were estimated based on the distribution of FRP benefits across all interventions considered in the included studies. For each income quintile, the FRP for every intervention was compared in that particular quintile and a higher weight (>1) was given to interventions where the FRP for that particular intervention in that particular quintile was greater than the mean FRP of all interventions in that quintile. Health outcomes (number of deaths averted) were then weighted with the FRP weight.

A league table was then compiled based on unweighted and weighted health benefits and cost-effectiveness by ranking all 145 quintile specific interventions. Using the rankings, an index was created to calculate the probability that a given budget funding N interventions would produce pro-poor distribution (where each quintile received same or higher proportion of interventions compared to richer quintile).

Unweighted rankings produced pro-poor allocations 67% of the time while FRP-weighted rankings were pro-poor 76% of the time. Proportion of interventions assigned to each income quintile based on weighted and unweighted rankings is shown in this figure from the published paper (Figure 3). Unweighted rankings prioritize quintile 3 for first intervention and distribution of interventions was higher for the richer 2 quintiles early on. The weighted rankings produce more equitable distribution.

The framework developed in this study contributes important insights into how health policy makers could prioritize cost-effective interventions to support the economically weaker parts of the society to receive more benefit. Although this approach requires several assumptions (linear scalability of interventions, ability to target specific quintile or quintiles, etc), it focuses on a nonpreference-based risk of illness rather than a social welfare function. Further research is required to see if results and conclusions of this framework would be generalizable.

RESEARCH ROUNDUP

Section Editor: **Aakash Bipin Gandhi, BPharm, PhD**, Methodologist Expert, RWD, Sanofi, Cambridge, MA, USA

The post pandemic future of work.

Malhotra A. *J Manag*. 2021;47(5):1091-1102.

Summary
The article by Malhotra summarizes the challenges faced by individuals and organizations in relation to the post-pandemic future of work. Additionally, the article also sheds light on the potential characteristics of the future of work and opportunities for future research that can help resolve challenges associated with these characteristics.

Relevance
The authors state that characteristics of the future of work in the postpandemic era may consist of the following elements. First, work may be mainly virtual in nature. This can create challenges for companies in terms of how they build, maintain, and sustain a desired level of organizational culture. This can be challenging when employees may not be working collaboratively in the same physical setting. Second, the future of work may require employees to work in highly matrixed organizations. This could be challenging for employees to navigate given they may need to alter between multiple reporting lines and go through multiple performance reviews. Third, the authors hypothesize that future organizations may need to hire "gig" or "freelance" workers for certain specialized tasks. Gig workers usually have the flexibility to work from any place at any time. In future organizations, this working arrangement may cause gig workers to be overworked to an extent that their job responsibilities begin to intrude on their work-family boundaries. Overall, this article aims to highlight characteristics and challenges associated with the future of work to encourage research on these topics and generate potential solutions.

Employment 5.0: the work of the future and the future of work.

Kolade O, Owoseni A. *Technol Soc*. 2022;71:102086.

Summary
The authors present a systematic review that describes the positive impact that digital transformation aims to bring to the future of work. Importantly, after considering existing theoretical and analytical perspectives, the article summarizes key factors that will impact the future of work from skills/creativity-related requirements to discussions around the potential for autonomous workers. Additionally, the article also describes how the future of work may be impacted by changing political and institutional processes and proposes associated directions for future research and potential interventions.

Relevance
In terms of directions for future research, the authors state that both developed and developing countries will be highly dependent on gig economies in the future. Hence, these countries should focus on developing novel models of workforce contracting that are suited to a gig economy setting. Further, policy makers and stakeholders in these countries should focus on implementing evidence-based interventions to overcome inequities introduced due to the process of digital transformation. These interventions may be implemented in the form of educational programs through academic institutions or by providing hands-on training and support to employees, autonomous workers, and business owners. In conclusion, the authors state that continued political organization and activism can help generate novel industries and markets which, in turn, can create employment opportunities for autonomous workers seeking to make informed decisions regarding employment suited to their skill sets.

Artificial intelligence and the future of work: a functional-identity perspective.

Selenko E, Bankins S, Shoss M, Warburton J, Restubog SLD. *Curr Dir Psychol Sci*. 2022;31(3):272-279.

Summary
The article by Selenko, et al discusses the potential impact of artificial intelligence (AI) on worker experiences. The authors propose a framework for the application of AI to an organizational setting and discuss how this may impact how people identify with work-related issues among other individual and societal outcomes.

Relevance
AI or associated processes may be beneficial for employees as it can help save time and effort with existing tasks. Conversely, it can also result in psychological harm for workers as it may eliminate certain tasks which no longer require manual or person-assisted labor. In this article, the authors state that the degree to which AI can either be beneficial or detrimental to a worker's identity is tied to the functional deployment of the technology. This means that it is important to understand whether the implementation of AI complements, replaces, or generates new tasks for existing workers. In conclusion, the authors state that the evolution of AI would require workers, organizations, and society to develop and implement certain frameworks to efficiently adopt and implement AI to aid and support beneficial growth.

Note from the Section Editor: *Views, thoughts, and opinions expressed in this section are my own and not those of any organization, committee, group, or individual that I am affiliated with.*

Can Wearable Devices Help Reduce Health Disparities and Add Value?

About the Author

John Watkins, PharmD, MPH, BCPS, Premera Blue Cross, Mountlake Terrace, WA, USA

COVID-19 lockdowns changed our lives overnight, eliminating the divide between people who had ready access to healthcare and those who didn't. Suddenly, *everyone* had barriers. Clinics closed and mobility evaporated. For a few weeks in the spring of 2020, all of us experienced frustrations that are daily life for many of America's poor. Through the pandemic, we learned what it is like to live without that access. We accepted workarounds including telehealth visits and other digital health technologies (DHT) as substitutes for in-person care. Often, it was our first exposure to telehealth and the technology that goes with it. Having seen a real-world demonstration of how these technologies can bridge access barriers, how will we use that knowledge to address disparities and improve access to care for all?

As one participant in the Innovation and Value Initiative Health Equity Initiative noted, "Equity is about removing barriers and obstacles to having just opportunity for health. If you have not worked to understand the social, cultural, and community drivers that affect people, then you are not assessing value."[1] DHT is transforming healthcare, reducing the negative impact of physical and geographical barriers.

As clinics reopened following the disruption of pandemic lockdowns, there was a shortage of physicians, nurses, and other health professionals due to burnout and early retirement. Not unexpectedly, payers saw a cost-trend rate increase driven by treatment of acute and long COVID, and by patients with delayed diagnosis of treatable conditions due to suspension of routine screenings caused by the pandemic. The global societal cost of long COVID alone has been estimated to be $2.6 trillion[2] and the direct medical cost $163 billion.[3] Much of this burden has fallen on the United States, making it more urgent to increase efficiency. Consumers demand transparency, and health systems are improving patient portals to provide more access to their electronic health records. These portals provide a ready connection point for home digital devices. With the decreasing cost and increasing power of hardware and software, we can expect a technology explosion.

Although COVID-19 has spread everywhere, statistics show substantially worse outcomes in lower income Black, Hispanic, and Native American communities, where vaccination rates were lower and crowded living conditions facilitated transmission. People in remote rural areas that already had difficulty reaching providers saw that access further limited. These barriers can be subtle or obvious. They are an integral part of social structures, including healthcare, and they will not be breached easily. Is digital technology up to the challenge? This article explores some of these barriers and suggests ways in which it could help address them. In addition to improving patient access to care, monitoring devices are expected to see expanded use in clinical trials, enabling direct measurement of endpoints that were previously unavailable to researchers and could be tracked only through patient and caregiver diaries. Clinicians and researchers must consciously work to include the voices of target patient communities in the design, implementation, and evaluation of projects, ensuring that the work aligns with their needs and priorities.

Barriers Separate and Isolate

Geography limits access. People in remote areas must drive long distances to see specialists. In rural Alaska, even basic primary care access may be unavailable in some communities at some times. Distance is not the only barrier. Many low-income urban residents do not own cars. Their trips to clinics or hospitals on buses and trains are often short distances that take a long time due to multiple transfers. This is challenging enough when one is healthy; it is more difficult for the chronically ill. Furthermore, low-wage workers may have difficulty getting time off for provider visits and may not get paid for missed work hours, adding financial stress to their health concerns. Less education and poor health literacy correlate with chronic disease,[4] and these individuals are subject to depression and reduced employment that add to their underlying medical problems.

Language and culture are common barriers in immigrant communities, where translators that can interpret cultural nuances and expectations may not be available. Even when language is understood, clinicians' advice is likely to be ignored if it conflicts with traditional health beliefs. For immigrants, allopathic medicine may be their last resort after familiar remedies have failed. For example, working in Nepal, I learned that traditional health beliefs based on Ayurvedic medicine classify diseases as either "hot" or "cold." Our patients wanted to know which foods they should eat while taking the drugs we gave them, so the pharmacy staff would add, "Don't eat hot (or cold) foods while taking this medicine," to the usual prescription counseling. This advice was medically meaningless and the choice of hot or cold random, but we hoped it would improve credibility and adherence.

Historical abuses of Black Americans by the healthcare system have created reasonable suspicions that impact willingness to seek care and impair trust in medical advice. A symposium speaker[5] recently described a documentary on gene therapy for sickle cell disease, in which the narrator had casually mentioned without further explanation that a lentiviral vector, which is a modified HIV virus, was used to deliver the gene. Recalling the infamous Tuskegee syphilis study,[6] a logical reaction from a Black person would be, "Great! First, you gave us syphilis—now you want to give us HIV!" There is a long history of such medical abuses and "separate and unequal" care. Cultural memories last for generations, and unintentional ignorance adds to justified distrust.

Ethnic and genetic characteristics mix to create heterogeneous populations, for which standard racial classifications used in medical records are insufficiently granular to guide clinicians and researchers. A person classified as "Hispanic" could be

White, Black, Native American, or any combination. Cultural beliefs and practices in Caribbean countries show African influence, while people living along the Andes inherit the beliefs of their ancestral native cultures. Geography and climate are radically different across Latin America, so it is unlikely that 2 cultures in different regions would share all the same health beliefs. Two individuals classified in this overly broad category may share no racial ancestry and have only the Spanish language, colored with local vernacular and pronunciation, and vestiges of Spanish colonial culture in common. If we are to seriously consider these patients' perspectives, more precise information is needed.

Home-Based Monitoring Can Improve Access

As the population ages, efficient secondary prevention for chronic conditions is needed. Home monitoring technologies, including in-home sensors and wearable digital devices, offer increasingly detailed and sophisticated continuous monitoring of patients. Artificial intelligence can interpret the results, disaggregate inputs, and filter noise. Continuous measurement gives a fuller picture than discreet data points collected at intervals during clinic visits, allowing the development of individualized strategies to manage patients' conditions, maintaining health and functionality, and potentially improving outcomes. Continuous glucose monitoring in diabetic patients is an early example of a well-developed mature technology that helps patients reduce hemoglobin A1c levels and avoid acute hypoglycemic episodes. Remote monitoring could help patients that have difficulty accessing clinics by reducing the need for in-person visits with their providers.

Physical activity is of critical importance to complex internal medicine patients and the elderly in general. Reduced mobility decreases overall health. Objective measurement can give clinicians a more realistic picture of the patient's daily patterns of movement and alert them when activity levels decrease, as is often the case after changes in medications or surgical procedures. This technology can also help diagnose and follow neurodegenerative diseases in the elderly, monitoring fall risk and the need for in-home assistance. Specialties that could benefit from applying digital monitoring include oncology, cardiology, immunology, endocrinology, pulmonology, neurology, psychiatry, geriatric medicine, and rheumatology.

Patients with Parkinson's disease would be prime candidates for this type of assistance since they suffer complex movement disorders, often accompanied by depression, cognitive decline, and sometimes psychosis. Patients can be monitored remotely for changes to functional status, response to changes in medication, and needs for in-home care. Pharmacotherapy for patients with late-stage Parkinson's disease involves a delicate balance of multiple medications, including those used to treat comorbidities. Home monitoring can quickly identify providers when a medication change has not improved things or has caused unwanted side effects.

We are a data-driven society. Increased computing power and memory, miniaturization, and artificial intelligence will expand the range of potential applications. As patients acquire "smart home" technology, it becomes easier and less costly to combine multiple devices, improving accuracy and sophistication of measurement. Payers must develop appropriate coverage criteria, and that will require new evaluation methods. Low-income individuals may need financial assistance to upgrade home infrastructure to support the technology.

Monitoring Can Improve Usefulness of Trial Outcomes

Potential applications of in-home digital monitoring in pharmaceutical research were explored in a recent ISPOR webinar series.[7,8] The safety and efficacy of many drugs depend on how they impact patients' functioning in a real-world setting, which is difficult to reproduce with in-clinic monitoring. Patient-reported outcomes are subject to reporting errors and may be colored by subjective experience. Combining objectives in-home measurements with patient-reported outcomes may provide a fuller picture by combining subjective and objective inputs. For example, Alzheimer's disease, a major target for drug development, produces changes in daily behavior and sleep patterns that are measured by patient and caregiver diaries. Patients with early stage dementia, although still capable of living independently, may forget to report things but appear alert and oriented in clinic visits. Direct measurement could give a clearer picture of how a drug regimen affects the patient. Current trial evidence for Alzheimer's disease drugs is frustratingly inadequate; it is hoped that digital monitoring will improve our understanding of their true effectiveness.

> Clinicians and researchers must consciously work to include the voices of target patient communities in the design, implementation, and evaluation of projects, ensuring that the work aligns with their needs and priorities.

Regulators must approve the endpoints in registration trials. This begins with agreement that the endpoint is an appropriate measure of the proposed clinical outcome. The accuracy of measurement of the monitoring device must be demonstrated, and its validity in the patient population and setting(s) of interest must be shown. For example, daily movement patterns of a person in a home setting might be different from those of the same individual in an assisted living facility. The device(s) must be acceptable to patients to wear long-term, and a device capable of multiple measurements would be preferable to multiple devices. The algorithms that analyze raw data must be validated (analytical validity—does it measure what we think we are measuring). Artificial intelligence will play an important role in refining this. Then, the developers must confirm that the measurement correlates with a clinical outcome of interest (clinical validity). These steps are required of any diagnostic and are relatively easy.

The final step, of greatest interest to payers and health technology assessors, is demonstrating clinical utility, which means that the use of the intervention in a population of interest produces overall net health benefit. Because clinical utility is not required in safety and efficacy trials, developers may have limited incentive to generate this evidence, which requires long-term, real-world use. However, if the specific measurement comes to be used for routine monitoring outside of trials, the manufacturer could collect and analyze data from large databases to produce the required real-world evidence.

The Voices of Lived Experience Are Essential

Patient centricity is supported by the Affordable Care Act, which created the Patient-Centered Outcomes Research Institute. The US Food and Drug Administration has emphasized including patients at earlier stages in the clinical drug development process. Researchers and technology assessors understand that value assessments must incorporate patient perspectives. Historically, research was based on what sponsors, investigators, payers, public health experts, and regulators thought was important. Recognizing patients was a crucial first step in the right direction, but we must move beyond thinking of patients as a homogenous group. Another Innovation and Value Initiative Health Equity Initiative participant observed, "If you don't see how race, income, gender, and other patient characteristics inherently drive value, then you are not assessing true value in healthcare."[9]

Individuals' and patient subgroups' perspectives may vary, and a collective approach usually underrepresents the perspectives and concerns of minorities. Information asymmetry negatively affects patient empowerment in these interactions, a problem that is magnified by the lower educational levels and power imbalance in minority communities. This is a problem we must address to achieve fair treatment for these groups.

Organized efforts to educate patient representatives can reduce the asymmetry. For example, the European Patients' Academy on Therapeutic Innovation (EUPATI) is a collaborative nonprofit organization that "provides education and training to increase the capacity and capability of patients and patient representatives to understand and meaningfully contribute to medicines research and development, and to improve the availability of medical information for patients and other stakeholders."[10] EUPATI graduates have impressive knowledge, understanding, and ability to engage in peer-to-peer conversations regarding their needs and concerns with health professionals, policy experts, and others. These conversations are enlightening and often expose erroneous presuppositions held by professionals.

Researchers must work in partnership with patients to incorporate lived experience from patients, caregivers, and communities, including groups that have been left out of the conversation. This is necessary to develop clinical trial designs and endpoints that more realistically reflect what matters to each patient. Are we asking the right research questions? Will the trial designs, populations, and endpoints produce the data needed to support minority patients' choice of the best treatment for them? The addition of objective endpoints collected by wearable devices and other in-home monitoring to clinical trial designs can provide a fuller picture of how an intervention actually affects patients if we choose the right endpoints and interpret them correctly. Adequate representation of minorities in trial populations will help us determine whether the intervention works for them as well as for the majority.

This sounds simple, but there is no agreement as to how to make it happen. People are incredibly diverse in so many ways that the one-dimensional data points in a clinical trial cannot be expected to do them justice. Whose voices should we listen to? How will we know when we have sampled enough? These are tough questions, but their difficulty does not excuse ignoring them.

Setting Priorities

To return to the original question, how can digital technologies help level the playing field of access and reduce health disparities? The Innovation and Value Initiative's Health Equity project is examining the relationship between health equity and value, with the goal of "elevating the national discussion" on this important issue from a societal perspective. The group's steering committee explains that "Health technology assessment advances health equity when it reduces health disparities by aligning access and affordability of healthcare technologies and services with the differing needs and values of diverse patient populations, especially those who are most marginalized."[1]

The conversation about value in healthcare has been dominated by payers, providers, health economists, and policy experts, but the patient is the ultimate judge of whether a healthcare intervention has value. All of us will agree that certain outcomes (eg, freedom from pain, adequate nutrition, mobility, etc) are important, but beyond these, priorities vary among and within different populations. When the population in question is a disadvantaged minority, it is especially important to listen with open minds and hearts, connecting and establishing credibility, and facilitating the necessary education and support to empower their participation as equals in the process. Viewing value assessment from the perspective of lived experience is complex when you consider ethnic, racial, cultural, and genetic differences among patients that share a common medical condition, but we must make the effort.

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ISPOR Conferences and Events

ISPOR 2023 | May 7-10

Boston Convention and Exhibition Center, Boston, MA, USA

Impacting Innovation, Value, and Healthcare Decision Making

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Monday, May 8 | 8:30AM EDT
Global Focus on Affordability and Inward Investment: What Does it Mean For HEOR?

Tuesday, May 9 | 8:30AM EDT
AI Wants to Chat With You: Accept or Ignore?

Wednesday, May 10 | 11:30AM EDT
Issues and Solutions When Estimating Treatment Effects Using US Electronic Health Record Data

A sampling of sessions along with hot topics from across the HEOR spectrum:

Health Policy
Improving Coordination Between the FDA and CMS: Exploring Potential Policy Solutions to Improve Patient Access to Drugs Granted Accelerated Approval

Drug and Healthcare Pricing
What Would (Should) CMS Do? A Debate on Options For Drug Price Negotiations

SPOTLIGHT SESSION: *Artificial Intelligence*
Larger, Deeper, and in Real Time: Applications of Machine Learning and Natural Language Processing on EHRs to Learn From the Patient Journey at Scale

Real-World Evidence
Standardized Assessment Tool Designed to Assist in Evaluation of RWE on Drug Effectiveness and Safety

Health Equity
Do We Need Advanced Modeling Methods for Equity-Informative Economic Evaluations?

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Submit an Abstract

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- Understand the need for systematic literature reviews and meta-analysis for comparative effectiveness research and healthcare decision making.
- Describe the steps to perform a systematic literature review and understand the statistical methods of combining extracted data by means of meta-analysis.
- Understand the advantages and limitations of meta-analysis, appraise meta-analytic reports, and decide whether to use the results.

April 26-27 | 10:00AM – 12:00PM EDT

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- Assess EHR-derived dataset fit-for-purpose given context and question.
- Identify key use-cases for applying EHR-derived data to fill evidence gaps for value assessment.

May 24-25 | 10:00AM – 12:00PM EDT

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ISPOR Education

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- Understand the difference between "open source" and "open access" models and become familiar with PRISM, a novel cloud-based model access platform.

May 31 | 11:00AM – 12:00PM EDT

Clinical Trial Innovation: How Healthcare Technology Is Evolving

What you will learn at this webinar:

- Understand how real-world data and diversity improvement can be leveraged in clinical trials.
- Learn how decentralized clinical trials are different from traditional trials, and how new technologies are enabling their use.
- Explore opportunities of introducing new technologies in healthcare.

June 1 | 10:00AM – 11:00AM EDT

Challenges in Rare Disease Diagnostics: An Overview

What you will learn at this webinar:

- Understand the challenges in diagnosing rare diseases.
- Discover the impact these challenges have on determining access and value.
- Reveal solutions to improve the situation.

June 8 | 9:00PM – 10:00PM EDT

Assessment of Digital Health Technologies in the Asia Pacific Region

What you will learn at this roundtable:

- Understand the perspective of a digital health developer on their experience receiving regulatory approval and reimbursement of digital health technologies.
- Hear from different countries or jurisdictions from the Asia Pacific region on the status of assessing digital health technologies.
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HEOR & THE FUTURE OF WORK

For the health economics and outcomes research (HEOR) industry—just like almost every other white-collar industry—the COVID-19 pandemic has changed the way people work and perceive their need to be in a physical office. As the pandemic wanes and industry conferences to go back to in-person events, some companies have asked their employees to head back to the office, at least for a few days of the week—and questions have grown around how to recruit talent and communicate, in a hybrid or fully remote setting, the intense scientific data most HEOR professionals are immersed in. ISPOR asked professionals in the corporate setting at IQVIA, GlaxoSmithKline, and Novo Nordisk their thoughts on what will happen in the future of work in this industry.

By Christiane Truelove

Home, Hybrid, and Beyond

According to Madeline Smith, Senior Recruiter, Talent Acquisition, at IQVIA, before COVID-19, some employees were able to work from home and because of this, "we were able to adapt pretty quickly and seamlessly to this more remote model."

One of the reasons why IQVIA offered remote work before the pandemic "is because we are trying to hire the best people with very specific qualifications. And for that reason, we don't want to limit ourselves to one office location, whether that be in Pennsylvania, North Carolina, or San Francisco, where some of our biggest offices are. But we've found talent in all of the nooks and crannies of the United States and Canada, and also globally."

IQVIA continues to offer a home-based working model that includes some travel (particularly for senior leaders), whether to conferences such as ISPOR or in-person client meetings and workshops. "Employees are statistically both happier and more efficient when they are given the choice to work from home," Smith says.

> "Employees are statistically both happier and more efficient when they are given the choice to work from home."
>
> – Madeline Smith

For Christopher Blanchette, PhD, Vice President and Head, Clinical Development and Outcomes Research at Novo Nordisk Inc, the past few years have brought about a lot of change. "We were an organization that was fully in house and, aside from our field teams, we all have an in-house, scientific role. Then the pandemic hit."

Right before the pandemic started, Blanchette took the job as the head of health economics and was asked to relocate to be closer to the company's New Jersey headquarters. "So, I moved to New Jersey during the pandemic, and then we went fully remote for 2 years or so. It's been interesting these last few years because we went through a long process of trying to get people comfortable with working remotely and engaging remotely. When we finally got into our groove, things started opening up."

Blanchette hired about 50% of his team during the pandemic and now leads a group of about 60 people. "A lot of people work remotely and we all learned how to work together." But when everything started to open up about a year ago, Novo Nordisk pushed for a hybrid concept and "people were encouraged to come in if they wanted to come in." For a while, only a small group of people were using the office, but "about once a month, we had a big group of people come in, and it was a bit like a reunion every month—they'd all go to dinner, attend team events, and have evening receptions. It was just a time to come together."

Recently, Novo Nordisk has communicated that being in person is part of the company's culture, as it fosters dialogue and discussion. "[The company] felt like we were missing out on that [in-person collaboration and connection], so now they've been a little bit more focused on getting people in the office and having more people engaged in the office, but still allowing for that flexibility," Blanchette says. Generally, the company wants people in the office 3 days a week, but people who were hired over the course of the pandemic can stay remote and commute in when they're needed.

While he enjoyed working remotely, and getting back into the office was a bit of a struggle, Blanchette says he likes the hybrid schedule. "I really enjoy where I am now, which is in the office 3 days a week—and then 2 days a week, I can decompress and work out a little bit longer in the mornings, and don't have that hour commute on the front end and the back end. I've got mostly the dedicated time where it's quiet and I can get work done. So right now, it's the optimal place for me to have a little bit in the office, a little bit at home."

As a young professional, Soham Shukla, PharmD, MS, Global Value Evidence & Outcomes Associate Director, Oncology at GSK, has been working for 3 and a half years—and the vast majority of that time has been working remotely. "I was only in the office for about 9 months, doing the traditional things in a pre-COVID style of working. Then we had to transition [to working remotely] and make all these different things work," Shukla says. "So, for me—and I imagine a lot of other young professionals who have been doing this for less than 5 years—working remotely is the norm. When we think about the future, we're also thinking that working remotely is what we're used to. If we were to go back to what we call 'traditional in-office work,' that would actually represent a big change for us that would need justification."

> "I really enjoy where I am now, which is in the office 3 days a week–and then 2 days a week I don't have that hour commute on the front end and the back end."
>
> – Christopher Blanchette, PhD

When it comes to remote work, GSK's philosophy is "performance with choice," Shukla says. "If during COVID, an employee got used to having to block off meeting time in the morning or afternoon so they could drop off or pick up their kids from school and then making up for that time in the evening, that was very acceptable."

But "it's taken a monumental effort at the individual team levels to figure out with HR all the other implications of where people are located, tax issues, and all that stuff that comes with it. So, many companies are putting in the effort to try to accommodate individual situations for each employee, which I think is the best attitude and approach to have."

The Personal Connection

Smith says she has talked to some job candidates who would like the option to go into the office. "So, we have some of our bigger offices open right now, and they're able to go in any time. But the work-from-home models have been working really well for us."

Shukla believes that there should be some in-office time as needed, especially for new employees, so that they can develop mentorships and relationships and "get to know people on a personal level, as opposed to a picture on a screen." But he also believes technology has helped "meet the talent where it's located. We might see a lot of analysts in India who are capable of working with real-world data. But we think of the hubs of the biopharmaceutical industry as being on the other side of the world, in the United States, or even on the coasts. But now people don't have to live in these regions to do the job."

Shukla says it's no longer taboo for job seekers to tell recruiters that they're not willing to relocate, or are willing to go in 3 days a week and work at home 2 days. "It's almost become templated [in the recruitment process], which I think is really interesting because before COVID, job seekers might think, 'Oh, am I going to be looked at as a less desirable candidate if I put all these conditions in?'"

> "If you live in the United States and you want to do HEOR for the United Kingdom, Spain, or one of the Asian countries, you don't feel like you're totally immersed in that environment...to really have everything 'click.'"
>
> – Soham Shukla, PharmD, MS

Blanchette says being able to use video technology in the recruitment process has been helpful. "If you think about the time and commitment, I can interview somebody that's in California and I've only consumed 45 minutes of their time, rather than having them fly all the way to New Jersey, stay in a hotel, and be away from their families. I think about the amount of time that we've gotten back in our life as a result of these new work dynamics."

As part of its talent development strategy, IQVIA offers internal and external training platforms to expand on soft skills and technical skills, Smith says. "We have multiple mentoring and coaching programs. Some of those are specific to the center of excellence. For example, we'll have mentorship programs within global epidemiology or HEOR. But we also have company-wide mentorship programs, that allow people to understand the business more cross-functionally." To promote that cross-functional networking, Smith says IQVIA has an internal platform called Career Connections, in which people can request specific mentors. "[Employees] can see who works where and what type of work they do. They're also able to utilize that platform to contribute to projects outside of their remit and see other career opportunities outside of their specific center of excellence as well."

Blanchette says remote technology also helped people more quickly develop relationships at Novo Nordisk and gave him more time to be present for his own team. "It's quite enabled our ability to talk to people in the field or in different parts of the organization very quickly. It has allowed for a lot more flexibility and freedom. It has given us a lot of time because instead of going to [corporate headquarters in Denmark] 6 times a year, now it's freed me up so I have more time to devote to people—both in Denmark and locally here as well."

The Limits of Technology

While there are many benefits to remote work, one thing Shukla has found it cannot offer to HEOR professionals is what he calls "immersion." "If you're generating HEOR evidence for the United States and you live in the United States, you understand everything about it—the healthcare system and all the different customers," he says. "But if you live in the United States and you want to do HEOR for the United Kingdom, Spain, or one of the Asian countries, you don't feel like you're totally immersed in that environment. And because the world is such a big place and everything's so different from each other, I don't think you get that true immersion that you need to really have everything 'click.'"

Before COVID-19, if members of a US-based team wanted to get immersed in the day-to-day realities of another country's team, they would just travel to that country or live there. "It was a relatively common part of an HEOR professional's career path in the pre-COVID times where, to learn about a different market, they might move to another country for 6-12 months for a type of rotational opportunity." Shukla says. "Whereas I feel now, we might think, 'Oh, we have Zoom or Teams to be able to talk to people who already live there.' So, is it really that we don't need these experiences? Or is it because we're conflating it with the other benefits of working remotely?"

The data-heavy nature of HEOR work poses challenges to remote and hybrid matrix teams in the industry, Shukla says. "We work on very sophisticated analyses, it can sometimes be seen as a little bit dry, or it's sometimes easy to get lost in details of it all."

Before COVID, data were reviewed in face-to-face meetings or small group workshops, "where we had people in a room and we're walking them through the story we're trying to tell, what data are really important, and why they should care about it," Shukla says. "Now, we're jumping on a Zoom call where you can be off video and muted and no one really knows if you're paying attention or understanding the message. That's going to really hurt some of the things we're trying to accomplish as we're trying to go through more complicated topics."

> "Through this process of COVID, as horrible as it was, one of the benefits is that it allowed us to rapidly apply our technology, which is going to have a positive impact moving forward."
>
> – Christopher Blanchette, PhD

When Blanchette was working fully remote, he found sharing data visually was the biggest challenge. "I'm a big, big drawer. I like to get on the whiteboard and sketch out study designs, methods, approaches, or the org chart. And that was difficult to do that during the pandemic and during working from home."

Because of these data-sharing problems, Shukla believes remote and hybrid teams need some kind of a dashboard for data visualization, which team members and even customers can interact with. Such a tool needs to be "fit for purpose for the data it's trying to show," he adds.

Looking Ahead

The future of work in the HEOR industry continues to evolve. As people get ready to head to the ISPOR conference in May, it may be the first time some of them have been in a large, in-person gathering for 3 years. Technology tools such as Microsoft Teams and Zoom kept HEOR groups together and working during the pandemic, but there were some difficulties in conveying the impact and complexities of the data being discussed. While these problems were mostly overcome, some people also yearned for the networking opportunities that face-to-face interaction generated.

Even with the resumption of days in the office and conference travel, the technology relied upon during the worst of the pandemic will continue to be used and will continue to evolve. For Blanchette, technology has cut his 6+ annual trips to Novo Nordisk's corporate headquarters to perhaps twice a year. While in-person meetings allow him to initiate conversations and make new connections, those relationships and collaborations continue through the use of digital technology. "Through this process of COVID, as horrible as it was, one of the benefits is that it allowed us to rapidly apply our technology, which is going to have a positive impact moving forward."

Note: Although the interviewees are employees of IQVIA, GSK, and Novo Nordisk, the thoughts expressed herein are their own and not the views and opinions of their employers.

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By the Numbers: The New Workplace

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Trends Driving Workplace Evolution of the Future

1. **Perception of the employee experience through the lens of a hyper-personalization strategy**
   - Built upon the integration of individualized distinctive experiences, which includes empathy towards employees and a greater focus on their total well-being.
2. **The need for digitally savvy talent is driving hiring decisions**
   - Combined with process automation within organizations, this leads to enhanced productivity. Organizations are operating in a hybrid world with digital literacy, competence, and dexterity being the key pivots for the future.
3. **Total well-being becoming a mainstream policy**
   - This is expanding from being a subheader within your benefit plan and is seeing sustenance through policy formulation and creation of an ecosystem driving systemic behavioral change. Leaders are developing skills to become more empathetic and sensitive to needs of employees.
4. **Shaping an organization's culture to support a virtual work paradigm shift**
   - This aspiration requires an integrated organizational view of culture across several aspects, such as workforce mix, digital aspirations, and agility. Hybrid work models have accelerated the movement towards an agile work culture.
5. **HR's focus on humanizing connection in a hybrid/virtual work environment**
   - This is achieved by helping organizations build emotional and relational capital as there is a need to preserve the social fabric of the organization by blending digital and human touch.

The 8 Cs+ Hybrid Leadership Model: A Checklist for Success

1. **CULTURE**
   Establish a healthy set of shared attitudes, values, goals, and practices
2. **CLARITY**
   Provide organizational direction and focus, while exhibiting transparency
3. **COMMUNICATION**
   Transfer or exchange information using various methods
4. **CHECK-INS**
   Follow a scheduled pattern of meeting and interactions to learn the status of your team
5. **COACHING**
   Accomplish by listening, asking questions, and helping your team think through and resolve situations
6. **COMMUNITY**
   Establish community–a unified group of people with a common interest
7. **CREATIVITY**
   Use imaginative skill or bring something new into existence to display innovation and creativity
8. **CARE**
   Show interest or concern

\+ **CAUTION**
Proceed with caution–exhibit awareness and continue to monitor the **8 Cs** to ensure that none are out of balance

Impact of Adoption of Artificial Intelligence on Healthcare Spending

Within the United States, wider adoption of artificial intelligence in research and healthcare could lead to:

$200 billion to $360 billion in **net savings** within the next **5 years**

$65 billion to $135 billion annual **reduction** in administrative **costs**

5% to 10% overall **reduction** in healthcare **spending**

These estimates were generated from AI algorithms.

Early Experience With Health Technology Assessments for COVID-19 Treatments

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HTA agencies prioritized assessments of COVID-19 treatments to facilitate patient access, conducting almost 80% of evaluations themselves that were undertaken between January 2022 and April 2022.

Nearly 80% of HTAs resulted in a positive recommendation; despite insufficient data, potential for high clinical benefit and high unmet need were key drivers of positive recommendations.

Economic evaluations were deprioritized in the assessments conducted, with only 1 cost-effectiveness analysis and very few budget impact analyses conducted.

Background

Over the past decade, the global healthcare market has seen an increase in the launch of health technologies.[1] New health technologies are approved daily, which may be attributed to aging population, rising income levels, emerging medical conditions, and advancements in knowledge and technology.[2,3] To assess how emerging therapeutic innovations perform compared to existing care, a standard policy tool is required to evaluate evidence across all dimensions.[4] Health technology assessment (HTA) is a multidisciplinary tool that systematically reviews the clinical, social, economic, organizational, and ethical evidence of a health technology to determine its value compared to standard of care. The valuation of the technology informs policy decision making, including reimbursement and pricing decisions, that facilitates access to healthcare innovations. Thus, HTA contributes to the maintenance of an equitable, efficient, and high-quality healthcare system.[4]

Emergence of COVID-19 pandemic severely impacted the healthcare sector with potential long-term impact on the conduct and operation of healthcare systems and technologies.[5] Examples of such impact included delay or disruption in the conduct of clinical trials, regulatory reviews, and inspections and audits of clinical trial sites as a result of restrictions imposed by travel bans, hospital/clinic visits, and social distancing precautions during the pandemic.[6,7] This research was conducted to understand the pandemic's impact on HTA and payer communities.

Methodology

A total of 15 HTA agencies, covering Europe, Canada, and Australia, were selected based on availability of assessment reports for evaluations undertaken between January 2020 and April 2022. Based on the completeness of information available, 9 of the 15 HTA agencies were retained for this research: Canadian Agency for Drugs and Technologies in Health (CADTH, Canada), Finnish Medicines Agency (FIMEA, Finland), Federal Joint Committee (G-BA, Germany), French National Authority for Health (HAS, France), Belgian Healthcare Knowledge Centre (KCE, Belgium), National Institute for Health and Care excellence (NICE, England), Scottish Medicines Consortium (SMC, Scotland), Dental and Pharmaceutical Benefits Agency (TLV, Sweden) and National Health Care Institute (ZIN, Netherlands).

> Only 1 appraisal (remdesivir submission to TLV) included a cost-effectiveness model. Budget impact models were included in 3 appraisals of COVID-19 technologies.

Relevant data to support our analysis for the selected agencies were extracted from the HTA Accelerator™ (HTAA), which is a comprehensive database that includes publicly available HTA reports. For the purpose of our research, we focused on the following information: assessment type, clinical evidence evaluated, economic model evaluated, drivers of cost-effectiveness, budget impact analysis performed, recommendation, and rationale.[8] A gray literature search was also conducted to identify any formal communication from HTA bodies describing their approach to prioritizing as well as any adaptation to processes for the appraisal of COVID-19 interventions.

Results

Overall, approximately 3200 evaluations were undertaken by the 9 HTA agencies selected between 2020 to 2022, of which a total of 91 evaluations (2.84%) were undertaken for various COVID-19 technologies for prevention, testing, and treatment. CADTH (n=36), NICE (n=22), and ZIN (n=13) conducted the most evaluations, while FIMEA, G-BA, and TLV undertook 1 evaluation each. No SMC and KCE evaluations of COVID-19 technologies were identified (**Figure 1A**). The majority of the evaluations consisted of horizon scanning reports

(28.6%), literature reviews of available evidence (27.5%), and clinical guidelines (17.6%) undertaken by HTA agencies; the evaluations assessed less innovative technologies approved in other indications that have been reassessed for COVID-19 treatment (**Figure 2**). Over the study period, only 24 HTAs were identified, with most appraisals for antivirals (33.3%) and monoclonal antibodies (29.2%) (**Figure 1B**).

Clinical guidelines and guidance issued by HTA agencies

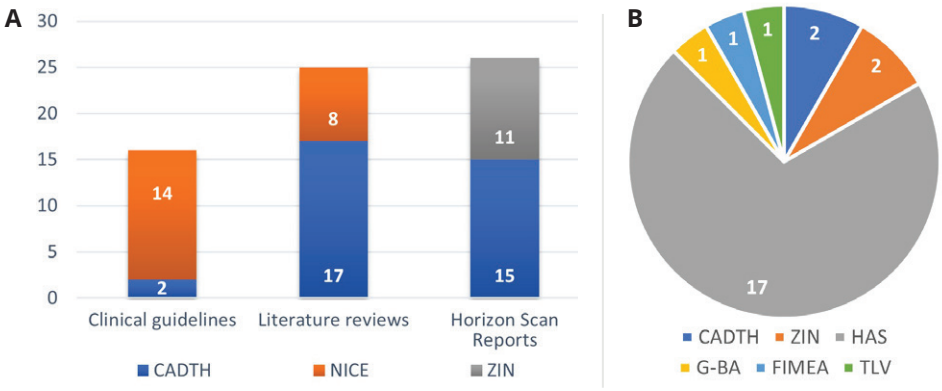
Guidelines and guidance issued by HTA agencies were published as horizon scanning reports (n=26), literature reviews (n=25), and clinical guidelines (n=16) by CADTH (n=34, 51%), NICE (n=22, 33%) and ZIN (n=11, 16%) (**Figure 1A**). Horizon scanning reports primarily focused on COVID-19 treatments (53.8%), such as monoclonal antibodies (casirivimab/imdevimab, regdanvimab, sotrovimab, bamlanivimab/etesevimab) and antivirals (remdesivir, favipiravir), while a few were for preventive or diagnostic procedures, testing kits, vaccines, wearable devices, and long-term post-COVID-19 conditions. Similarly, most literature reviews (64%) focused on treatments such as interleukin-6 antagonists (sarilumab, tocilizumab, anakinra) and steroids, while the rest were summarizing evidence on testing kits and procedures. The majority of the clinical guidelines (56.3%) were evaluated by NICE as rapid guidelines on potential treatments for COVID-19 (steroids, immunosuppressants, antibiotics, antimalarials, antivirals, vitamin D). Additionally, few other evaluations were conducted for COVID-19–related complications, respectively for cardiovascular (n=2), digestive (n=1), respiratory (n=2), and blood and immune disorders (n=2) assessed by CADTH, NICE, and ZIN.

None of the horizon scan reports, literature reviews, and clinical guidelines published in 2020 and 2021 provided recommendations; reasons for not making recommendations included limited evidence resulting in uncertain clinical benefits, limited generalizability to local clinical settings, and uncertain budget impact. In April 2022,[a] only 1 clinical guideline that reviewed pharmacological therapies for COVID-19 provided a positive recommendation with restriction from CADTH.[b]

HTAs of COVID-19 treatments

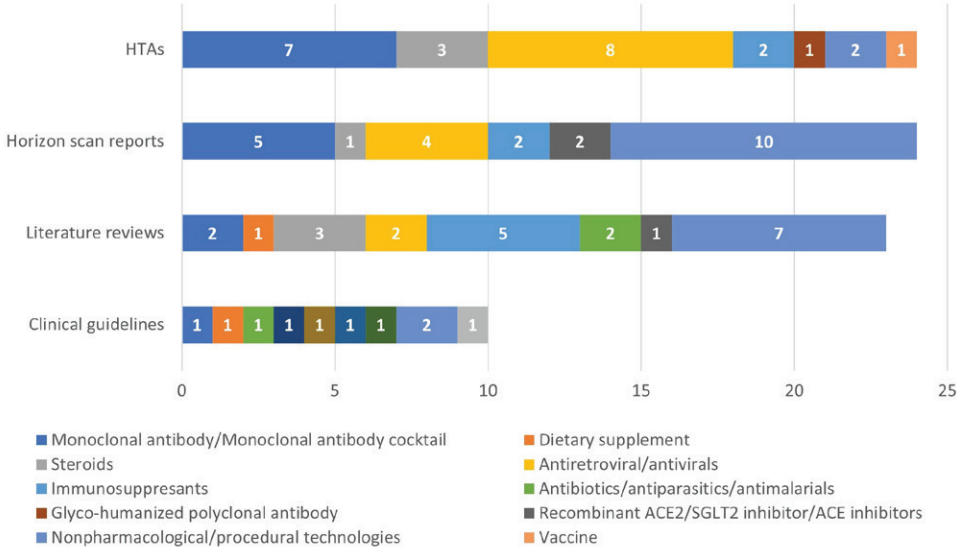
Of the 24 HTAs on COVID-19 treatments undertaken between 2020 and 2022, 16 appraisals were submitted to HAS (67%), and 2 were submitted to CADTH (8%), while 1 each was submitted to FIMEA (4%), G-BA (4%), and TLV (4%) (**Figure 1B**). Additionally, 1 appraisal for medical device was submitted to HAS and 2 procedure appraisals to ZIN. A total of 13 HTAs received positive recommendation, 6 received positive recommendation with restrictions, and 3 received negative recommendation, while 2 received no recommendation (**Figure 3A**).

Figure 1: Number of published evaluations by HTA agency: (A) Guidance and guidelines issued by HTA agencies (B) HTAs



CADTH indicates Canadian Agency for Drugs and Technologies in Health; FIMEA, Finnish Medicines Agency; G-BA, Federal Joint Committee; HAS, French National Authority for Health; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence; TLV, Dental and Pharmaceutical Benefits Agency; ZIN, National Health Care Institute.

Figure 2: COVID-19 technologies by evaluation type



ACE indicates angiotensin-converting-enzyme; HTAs, health technology assessments; SGLT2, sodium-glucose co-transporter 2.

[a] Restriction criteria were not made public and the decision rationale was specified as "no new information provided."
[b] The therapies evaluated were budesonide, dexamethasone, fluvoxamine, chloroquine, colchicine, lopinavir + ritonavir, tocilizumab, hydroxychloroquine, ivermectin, sarilumab, baricitinib, remdesivir, bamlanivimab, sotrovimab, nirmatrelvir+ritonavir.

Remdesivir was one of the most commonly evaluated treatments (16.7%); only HAS and G-BA recommended remdesivir but restricted its use to a subgroup of patients,[c] while FIMEA and TLV did not provide a recommendation for remdesivir. FIMEA and TLV noted that remdesivir shortened recovery time and potentially reduced mortality versus placebo and can be considered cost neutral if it shortens hospitalization by an average of 3 days. Tixagevimab/cilgavimab (pre-exposure prophylaxis), casirivimab/imdevimab (post-exposure prophylaxis and treatment for COVID-19), and sotrovimab (treatment for COVID-19) received positive recommendation based on clinical benefit and innovative nature of the products. Nirmatrevir/ritonavir for treatment of mild-to-moderate COVID-19 was recommended based on clinical benefit, good safety profile, and unmet need. Tocilizumab was recommended for treatment of COVID-19 based on clinical benefit but restricted to adult COVID-19 patients who require oxygen supplementation and had received prior systemic corticosteroid therapy (**Figure 3B**). Molnupiravir, XAV-19, and anakira received a negative recommendation from HAS based on uncertain clinical benefit.

Evidence included in COVID-19 evaluations

The clinical guidelines and guidance issued by HTA agencies were primarily informed by systematic reviews (n=29); other sources of evidence included randomized controlled trials (n=18), observation/cohort data (n=16), meta-analyses (n=5), and expert opinion (n=1). Few evaluations included budget impact models, undertaken by CADTH (n=12) and ZIN (n=7) (**Figure 4A**).

Clinical evidence submitted for HTAs was informed from randomized controlled trials (n=18), observation/cohort data (n=6), meta-analysis (n=5), expert opinion (n=3), early/expanded access trials (n=1), and systematic reviews (n=2). In terms of economic evidence, only 1 appraisal (remdesivir submission to TLV) included a cost-effectiveness model. The drivers of cost-effectiveness were the cost of treatment and associated treatment effect. Budget impact models were included in 3 appraisals of COVID-19 technologies only, to TLV (n=1), FIMEA (n=1), and G-BA (n=1) (**Figure 4B**).

> Economic evidence was deprioritized in the assessments of COVID-19 interventions, possibly to facilitate patient access. The aftermath of the pandemic highlighted a clear need for early cross-functional stakeholder collaboration.

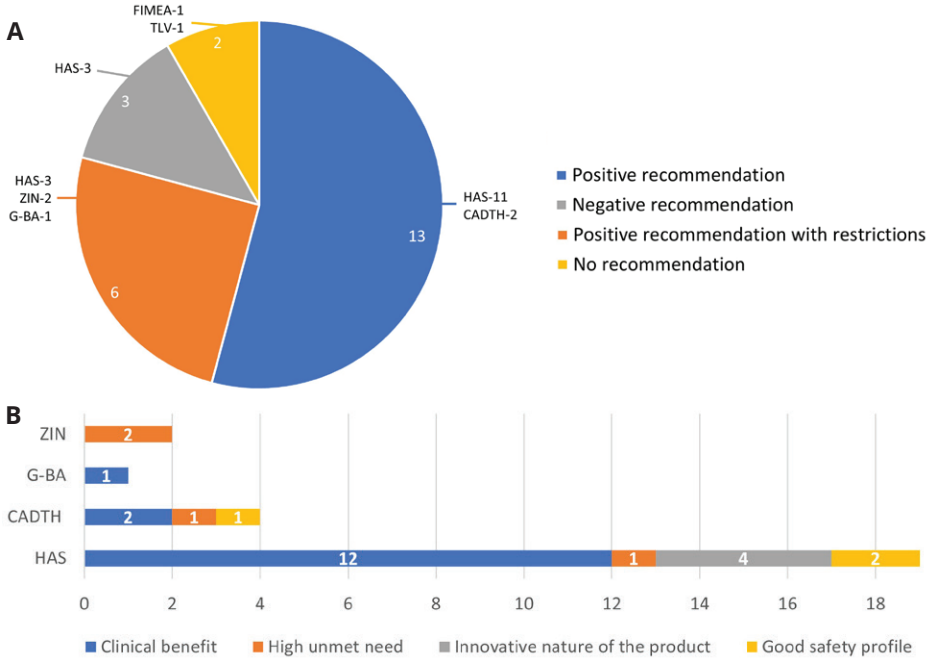
Prioritization and changes in timelines

Gray literature search revealed that NICE, HAS, and CADTH prioritized COVID-19 interventions as therapeutically critical.[9,10] NICE reported delays due to suspension of all appraisals during the first and second quarters of 2020, which led to a 25% drop in HTA publications in 2020 compared to the average in previous years, 2015 to 2019.[6] In April 2020, CADTH postponed planned drug review consultations; however, CADTH managed to continue operating with minimal impact on core and additional COVID-19 activities. CADTH, G-BA, and HAS moved to a virtual office to continue delivering programs and services.[9,11] SMC had stated that COVID-19 interventions were prioritized; however, no individual appraisals undertaken by SMC were identified as the agency collaborated with NICE and other organizations in the United Kingdom under the program for "Research to access pathway for investigational drugs for COVID-19" (RAPID C-19) to monitor and evaluate emerging trial evidence of potential COVID-19 treatments during the pandemic.[12,13]

Conclusion

Between 2020 and 2022, approximately 3% of the overall evaluations undertaken by the selected 9 key HTA agencies were

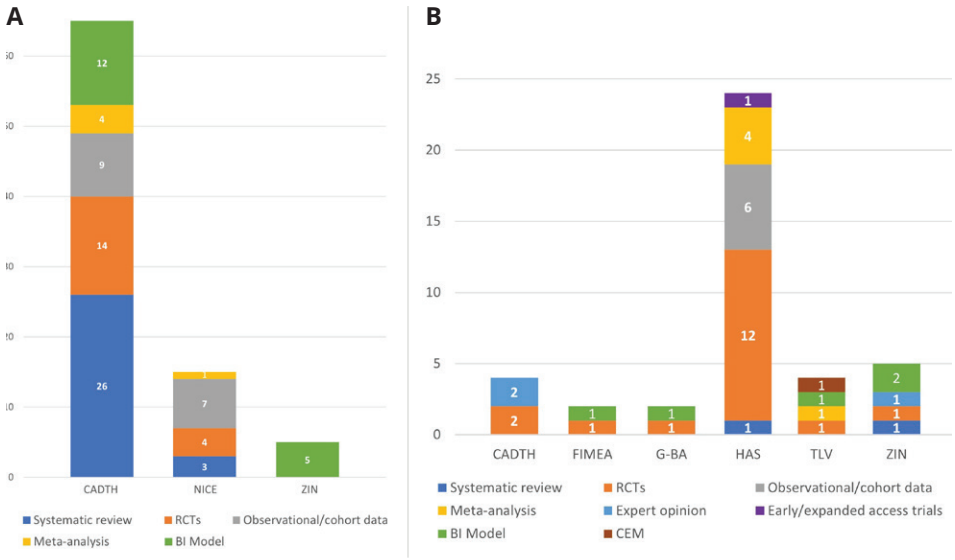
Figure 3: (A) Recommendations provided for HTAs; (B) Rationale for positive recommendations by HTA agency



CADTH indicates Canadian Agency for Drugs and Technologies in Health; FIMEA, Finnish Medicines Agency; G-BA, Federal Joint Committee; HAS, French National Authority for Health; HTA, health technology assessment; TLV, Dental and Pharmaceutical Benefits Agency; ZIN, National Health Care Institute.

[c] G-BA and HAS restricted use to patients aged 12 years or over, weighing at least 40 kg, hospitalized for COVID-19 with pneumonia requiring low-flow oxygen therapy, and at dosages as per the market authorization.

Figure 4: Type of clinical and economic evidence used by each HTA agency: (A) Guidance and guidelines issued by HTA agencies (B) HTAs



BI Model indicates budget impact model; CADTH, Canadian Agency for Drugs and Technologies in Health; CEM, cost-effectiveness model; FIMEA, Finnish Medicines Agency; G-BA, Federal Joint Committee; HAS, French National Authority for Health; HTA, health technology assessment; ITC, indirect treatment comparison; NICE, National Institute for Health and Care Excellence; RCTs, randomized controlled trials; TLV, Dental and Pharmaceutical Benefits Agency; ZIN, National Health Care Institute.

of COVID-19 technologies. HTA agencies prioritized COVID-19 and evaluated data available on potential treatments; out of the 91 evaluations identified, 67 were horizon scanning reports, systematic literature reviews, and clinical guidelines issued by HTA agencies. Most of these evaluations considered less robust data than what the HTA community is accustomed to, with only 18 evaluations including randomized controlled trial evidence; however, almost exclusively no recommendations were made in the January 2020 to April 2022 period due to lack of sufficient data.

On the contrary, the majority of the HTAs submitted (~80%) received a positive recommendation (with/without restrictions), although a very limited number of the submissions included an economic assessment which is a strong evidence requirement of all HTA agencies (1 cost-effectiveness model and 3 budget impact models only were submitted). Clinical evidence submitted was of good quality, with 18/24 submissions including randomized controlled trial data that potentially led to positive recommendations as the majority of positive recommendations were made due to demonstrated clinical benefit (79%), followed by high unmet need and innovativeness of technology (21%). With the health crisis brought in by the pandemic, research and development activities for testing, prophylaxis, and treatment of COVID-19 were prioritized by manufacturers, regulatory, and HTA agencies, leading to a majority of submissions being reviewed with less robust evidence. Economic evidence was deprioritized in the assessments of COVID-19 interventions, possibly to facilitate patient access. There was limited evidence available to assess the impact of prioritization and adaptation of COVID-19 health technologies by HTA agencies.

The aftermath of the pandemic highlighted a clear need for early cross-functional stakeholder collaboration and integration of processes for regulatory review and HTA to ensure access to high value innovation.

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What Will the Legislative Proposal for Joint Work on European Health Technology Assessment Approach Mean for Access in Europe?

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Oncology products and advanced therapy medicinal products will be the first products undergoing joint clinical assessment in 2025.

Despite joint clinical assessment, reimbursement decisions remain with the country and the impact on equality of access is unclear.

Timelines for dossier submission could prove challenging, requiring HTA work to begin before a medical product receives market authorization and has a confirmed label.

Introduction

After considerable discussions, the European Commission voted in March 2021 to adopt the regulation that would see joint clinical assessments on health technologies across Europe.[1] This will provide valuable scientific information to national health authorities, harmonize the approach to assessment across Europe, remove redundancies in the system, and provide support to countries that may lack the resources or infrastructure to undertake such assessments on their own. Joint clinical assessments (JCAs) are at the core of the health technology assessment (HTA) regulation. JCAs will be limited to the clinical comparative review of the technology, while member states remain responsible for economic aspects of HTA, drawing conclusions on added value for their health system, and making decisions on pricing and reimbursement.[2]

The transition period was set for 3 years to ensure preparedness from all stakeholders. Therefore, JCAs and joint scientific consultations will begin assessments, initially for oncology products and advanced therapy medicinal products, in January 2025. The next stage will include orphan drugs in 2028, with medicinal products from other therapeutic areas following 2 years later.[2]

In contrast to medical products, the joint work for medical devices will not follow the progressive implementation approach. Instead, the focus will be on high-risk medical devices (eg, class III implantable devices). A coordination group formed of expert panels will decide which medical devices to start with (the evaluation of low-risk medical devices will remain at a national level). The JCAs for the medical devices in scope will not start before 2030.[3]

After the initial agreement in March, Ipsos fielded an online survey in June 2021, with 35 payers from the Ipsos payer panel (eg, France, Germany, Italy, and Spain) and 13 respondents with global/European remit for market access at multinational pharmaceutical companies. The goal was to gather stakeholder views on the proposal.

Discussion

While the member states will be obliged to use JCAs for qualifying medical products and devices, additional clinical and nonclinical assessments will be permitted, while national HTA assessments for drugs not in scope will be required to run concurrently.[2] This brings into question whether the regulation would actually improve the availability of innovative technologies and the equality of access for patients across Europe. As certain therapies will continue to be assessed via national process until 2030, making comparisons across therapy areas potentially challenging given the differences in process and focus between countries and their JCA approach. As agreed in the development of JCA, the decision whether to fund and the acceptable price level to enable funding will remain a matter for the countries to decide.[2] Hence, the impact of JCAs—while standardizing the clinical assessment process—may not result in the ultimate goal of equality of access in Europe. This was highlighted in our survey as a key driver for stakeholders, as access will be discussed and agreed on a country level depending on the value to the member state's healthcare system.

> Overall, the survey results indicate that the HTA regulation may potentially improve alignment between countries and increase equality in access to therapies across Europe.

In line with the goals of JCAs, our payers saw greater equality to access across

Europe as a key advantage of the process (**Figure 1**). Industry respondents also expected streamlined processes; however, it should be noted that they appeared much less informed about the changes. Equally, the proposals resulted in some concerns from both the payer and industry perspective, with the areas of disadvantage noted being lack of country control/perspective from the payers (**Figure 2**). Industry respondents were most concerned about the duplication of HTA processes and the additional administrative burden, in addition to the lack of country control. Despite concerns, the majority of payers (86%) felt this provided an opportunity to ensure more equality of access across Europe.

As oncology and advanced therapy medicinal products will be the initial focus of the program, there are immediate areas that will require alignment including, but not limited, to:

- Differing standard of care
- Acceptance of endpoints
- Performing indirect comparison
- Assessing the added benefit with no direct comparator
- Dealing with single-arm studies

Although EUNetHTA has previously done work developing methods for the joint assessments, those were not meant to replace national HTA assessments. Since member states require different information for decision making, the disparity in requirements among member states is an impediment to the development of a joint submission dossier template. Other organizational challenges include developing a template for JCAs that is tailored to the needs of each member country, as well as defining the scope of the JCA.

What EUnetHTA 21 & Heads of Agencies Group are doing to address these challenges

EUnetHTA 21 joint consortium will provide support to the future European HTA system to be established according to the upcoming regulation. The consortium is led by ZIN (The Netherlands) and includes 12 EU HTA agencies.[4]

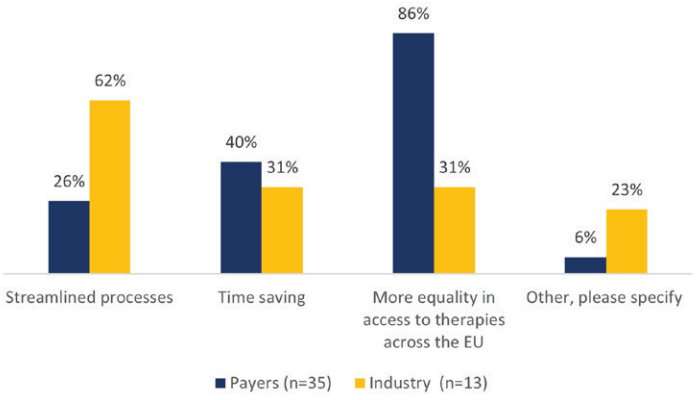
Member states already carried out some joint assessments in the past, which were performed alongside the usual national HTA assessments, and previous analysis indicated these had little impact on the national processes. This was demonstrated by the time it took to obtain reimbursement following an EUnetHTA assessment, which varied by member state, implying that member states primarily focus on meeting national requirements when evaluating new medicines.[5] Given the progressive implementation of the regulation, the national HTA system will have to keep ensuring the adequate assessment of other drugs. Both industry respondents and payers noted additional administrative burden and expanded time to approval as disadvantages of the joint clinical HTA process (**Figure 2**). The need to continue running standard national-level assessments of drugs outside the initial scope of the JCAs—while also designating members for a Coordination Group that would carry out JCAs and joint scientific consultations—is likely to become a resourcing challenge, potentially delaying patient access to new medicinal products.

A recently formed initiative, the Heads of Agencies Group,[6] will work during the next 3 years alongside the EUnetHTA 21 joint consortium to support the implementation of the HTA regulation. Current members of the group include 19 national authorities involved in HTA activities. The group will focus on supporting the preparation of national systems and capacities, as well as championing the work performed by the technical and scientific collaborations of HTA bodies across Europe. In addition, it will advise policy makers and national organizations on matters related to HTA.[5] It remains to be seen whether such collaborative efforts will be sufficient to tackle prospective resourcing issues of member states and thus ensure timely HTA assessments.

JCA dossier submission timeline

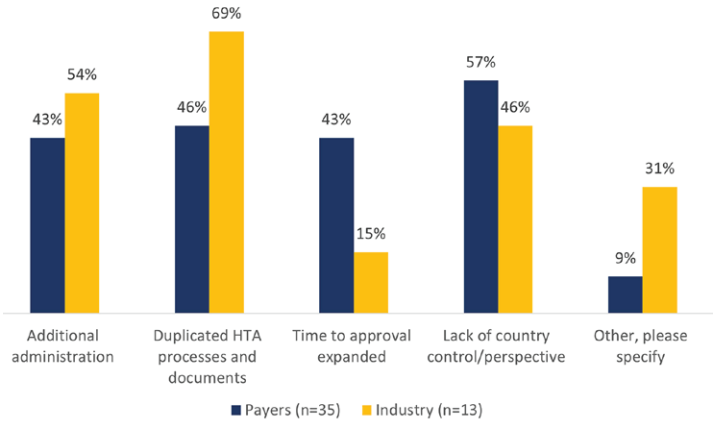
JCAs are subject to strict timelines to ensure that access to medical products is not hampered in member states. To meet the demanding timelines, the regulation requires health technology manufacturers to submit JCA dossiers at the latest 45 days prior to the envisaged date of the opinion of the Committee for Medicinal Products for Human Use (CHMP), while the Coordination Group is to endorse draft reports no later than 30 days following the

Figure 1: Perceived benefits of a joint clinical HTA process



EU indicates European Union; HTA, health technology assessment.

Figure 2: Perceived disadvantages of a joint clinical HTA process



HTA indicates health technology assessment.

marketing authorization.[2] However, starting HTA work before a medical product receives market authorization is quite controversial because the product may not receive a positive opinion from CHMP, meaning all work done by the Coordination Group up to this point has been a misallocation of precious joint resources. In addition, the recommendations for the final treatment label and specific conditions for use are granted by CHMP, which means that some critical aspects for assessment are not affirmed at the time of JCA dossier submission.

Will smaller countries be willing to accept the compromises required more readily than those with well-established HTA systems?

Member states that did not have an established HTA system or resources in place might be more willing to accept the format, guidelines, and methodologies of the regulation to improve the assessment of medicinal products brought to their markets. Many have already shown the willingness to look outward.

"The adoption of this law is another demonstration of how EU countries, when acting together, can achieve very practical results for their citizens. This new law will benefit patients, producers of health technologies, and our health systems," said Janez Poklukar, the Slovenian minister for health.

In contrast, countries with more established HTA systems might be less willing to compromise on country-specific regulations and principles in favor of JCAs. This means that, following the JCA process, member states may impose complementary clinical analysis for national HTA processes—potentially delaying patient access to new therapies, a concern highlighted in the survey results (**Figure 2**).

Given that the regulation's focus is clinical assessment, the nonclinical (economic) assessment will be left to the national HTA process. This leads to the question of how, if at all, JCAs would affect a country's ability or willingness to reimburse and thus influence equality of access.

Conclusion

Overall, the survey results (as well as positive views from member states) indicate that the HTA regulation may potentially improve alignment between countries and increase equality in access to therapies across Europe. The collaborative efforts are already taking place to address methodological and organizational hurdles. For instance, members of EUnetHTA 21 are working on development of draft methodological guidelines to be adopted by the Coordination group, while members of the Heads of Agencies Group are focusing on supporting the preparation of national systems. Consequently, despite the existing challenges, the collaborative work and engagement of all member states provide JCAs with the potential to improve equality of access for patients across European markets (which is in the interests of all stakeholders) and streamline processes for the industry and member states.

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Opening Up a Discussion on Biosimilar Value Assessment

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Value assessment of biosimilars should be pragmatic while being based on pharmacoeconomic principles and tailored to the specific setting where these medicines are used.

New biosimilar entrants can differ from already reimbursed technologies in their strength, pharmaceutical form, administration route and devices, and in the indications licensed. More elaborate guidance is needed on how to account for these differences at the HTA level.

If there is any intention to claim superiority or a price premium with a new biosimilar versus its competitors, manufacturers must think about the evidence package to support that early and communicate that value with stakeholders well in advance of launch.

Background

A few months ago, the ISPOR Biosimilar Special Interest Group (SIG) had the pleasure of organizing a forum on biosimilar value assessment at the ISPOR Europe Conference in Vienna. It was an ideal opportunity to present key learnings from our research project and to open up a conversation with the conference audience on knowledge gaps and challenges that relate to assessing biosimilars value. It was central to this session to discuss what has been and what is the foreseen role of health technology assessment (HTA) for biosimilars, and to question whether biosimilars value assessment should be restricted to a price comparison between the reference biologic and the biosimilars. The main highlights are summarized in the sections below.

A trend toward streamlining biosimilars value assessment: key considerations

According to our SIG's research investigating the role of HTAs for biosimilars, there has been a general aim to streamline biosimilar value assessment, mainly to make biosimilars more readily available for patients and to decrease the workload that HTA institutions are subjected to. Simplifying value assessment processes for biosimilars has generally implied circumventing formal HTA submissions and, when possible, basing reimbursement decisions on price comparisons.

Although it can be convenient to streamline the assessment of biosimilars, it is also necessary to determine which cases would require more detailed assessments. In fact, our research tells us that some circumstances may require conducting economic evaluations for new biosimilar entrants at the HTA level. For instance: (1) when the originator has not been approved for reimbursement before having to appraise new biosimilar entrants in a specific country; and (2) when biosimilars have different formulations and administration routes with respect to the originator. In the first case, the nonreimbursed originator will not likely qualify as a policy-relevant comparator for the new biosimilar entrant, and comparators with different active molecules and potentially different cost-effectiveness profiles may be selected. In this context, a proper comparative assessment of these technologies would require a full economic evaluation. In the latter case, relying on a simple price comparison for products with different formulations or administration routes may not provide a full picture of the real-world value of biosimilars.

> There has been a general aim to streamline biosimilar value assessment processes, mainly to make biosimilars more readily available for patients, and to decrease the workload that HTA institutions are subjected to.

Beyond price comparisons

Our research suggests that applying HTA methodologies to biosimilars can generate additional evidence on the value proposition of these products (**Figure**). So far, the lack of an established HTA pathway for biosimilars in certain jurisdictions has limited the potential to valorize broader elements of value, such as the provision of value-added services, extending the offer of marketed formulations and devices, and supporting supply-chain reliability. During the session, members of the audience expressed their interest in valorizing these aspects, especially when it comes to the differential provision of value-added services by sponsors.

However, in practice, several challenges relate to going beyond basing reimbursement decisions for

The ISPOR Biosimilar SIG Key Project

Given that there is debate about how to assess the value of biosimilars, the aim of the ISPOR Biosimilar SIG Key Project has been to investigate knowledge gaps concerning the HTA of these products. In order to identify and explore these knowledge gaps, a series of internal meetings were held among members of the SIG leadership team to develop a research strategy.

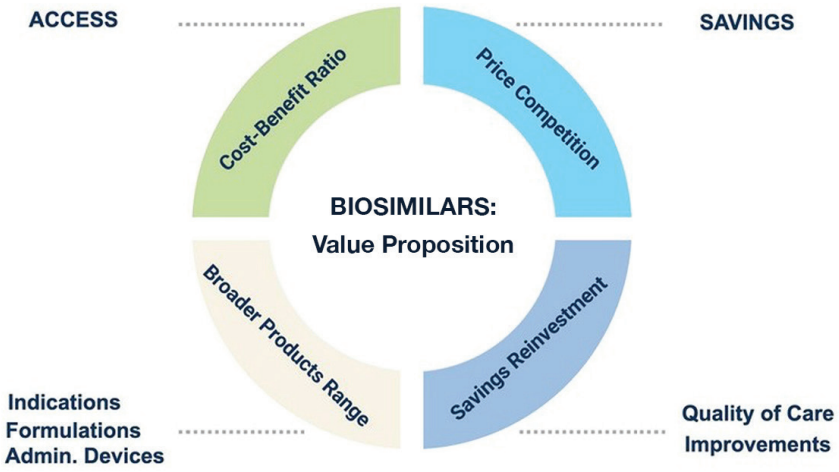
In a first step, a systematic review was conducted of peer-reviewed literature in PubMed, EMBASE, Web of Science Core Collection, EBSCOhost Business Source Complete; and of the gray literature. The analysis of literature data led to the identification of a number of methodological challenges associated with assessing the value of biosimilars. In a second step, it was necessary to investigate whether HTA agencies find these challenges relevant and how they have addressed them in practice. Semi-structured interviews were conducted and finalized in 2022, gathering insights from 20 HTA experts from Asia, Africa, Australia, Europe, and America.

Data relative to this SIG Key Project have been presented at the ISPOR European Conferences in Copenhagen and Vienna, and at the ISPOR International Conferences in New Orleans and Montreal. The manuscripts reporting on the outcomes of the systematic literature review and of the interview study are in the process of being published.

biosimilars on price comparisons. Some of the biggest challenges are the limitations in data availability. From the perspective of lower income countries, if value assessment goes beyond price comparisons, it may be hindered by limited available data or—in the case of emerging countries—limited HTA capacities. When reflecting on potential claims of added value submitted by biosimilar sponsors for reimbursement, biosimilars are often launched with the minimal data package to support regulatory approval. If there is then the desire to claim a price premium (say for example, on the basis of ease of administration), then there needs to be an appropriate evidence package to support that. So, a challenge is making sure that data are available to make a robust decision.

In view of these challenges, it is still in question whether it would be feasible to account for these broader elements of value at the HTA level. In accordance with the mission of our SIG, which is to discuss emerging issues of biosimilars focusing on health economics and outcomes research and reimbursement policy, we will continue to monitor new developments in biosimilar value assessment and to investigate solutions to current challenges.

Figure.



Our Special Interest Group has the pleasure to launch a series of interviews with key opinion leaders.

What is our aim?
We want to provide an overview of the current landscape of biosimilars and foster a deeper understanding of their benefits and challenges through the eyes of experts in the field.

Who is our target audience?
Academics, healthcare professionals, policymakers, and the general public audience interested in learning about biosimilars and their impact on patient care and healthcare systems.

Stay tuned to our ISPOR Biosimilars SIG Community platform for more details coming soon!


Poppy King

Q&A

Recruitment in the New Workplace: Interview With Poppy King, Talent Specialist for Asia Pacific

Section Editor: **Marisa Santos, PhD, MD**, Instituto Nacional de Cardiologia, Rio de Janeiro, Brazil

In keeping with this month's theme, I had the opportunity to interview Poppy King, Team Sales Manager at Barrington James in Singapore, to talk about recruiting talent in the new workplace model. In her role, Poppy works to pair director-level talent in health economics and outcomes research (HEOR), market access, and pharmaceutical consulting roles across Asia Pacific.

My interview examines how the pandemic has changed workplace models and recruitment practices around the world and explores how new collaborations, new technologies, and essential skill sets that employers are looking for impact hiring practices in the Asia Pacific region.

"Increasingly, health economists are looking beyond traditional economic analysis to consider the social, political, and ethical aspects of healthcare. Apps have enabled employers to easily track and manage the progress of their recruitment efforts, providing valuable insights into the effectiveness of their recruitment strategies."

– Poppy King

Value & Outcomes Spotlight: **The COVID-19 epidemic posed numerous difficulties for the pharmaceutical sector but also gave rise to many advancements, particularly in the area of remote work. Fieldwork for HEOR research requires collaboration. What do you think about the new partnership strategies?**

Poppy King: The health economics landscape has changed significantly in recent years. Increasingly, health economists are looking beyond traditional economic analysis to consider the social, political, and ethical aspects of healthcare. This shift has been spurred on by the move towards value-based healthcare, which takes into account both clinical and financial outcomes. Health economists are also incorporating new and emerging data sources, such as big data and artificial intelligence, to develop innovative models and insights. Additionally, the globalization of health economics has led to increased research collaboration and the emergence of global health economics networks. Finally, the rise of digital health has created new opportunities for health economics research, such as the study of health technology adoption and diffusion.

I believe the partnership strategies are designed to enable a more collaborative ecosystem between the pharmaceutical business and the payer, engaging all areas of the healthcare network in the local countries to demonstrate value and evidence efficacy—over the more traditionally focused access in a commercial sense—post COVID. Partnerships are an important part of the pharmaceutical industry in Singapore and Asia Pacific. Pharmaceutical companies partner with local research institutes, universities, and other organizations to develop innovative drugs, treatments, and medical technologies. In addition, they partner with other companies across the globe to share resources and leverage their expertise. These partnerships allow them to stay competitive in the global marketplace.

VOS: **Can you discuss a few of the specific changes that you've seen over the past few years, and describe how social media and apps have affected hiring in the pharmaceutical industry?**
PK: The rise of social media and apps has had a major impact on the pharmaceutical industry, allowing recruiters to reach a larger and more diverse audience more quickly and cost-effectively. Companies are now able to advertise job openings and promote their products and services to a broader range of potential customers and employees. Additionally, social media and apps have enabled recruiters to quickly source qualified candidates, enabling them to save time in the hiring process.

These platforms have allowed us to build a narrative and promote the branding backgrounds. Finally, apps have enabled employers to easily track and manage the progress of their recruitment efforts, providing valuable insights into the effectiveness of their recruitment strategies.

Previously for global or regionally focused hires, candidates would have to wait a significant amount of time between interviews to meet a key decision maker, largely due to geographical remit. With the apps and technology, meeting talent is being expedited.

> I do anticipate and have started to witness a shift back to a more hybrid 60% to 80% office-based model due to the increasing need for social and collaborative interactions and information sharing.

It's important to understand that with every upside there is also a downside: increased speed and agility to apply at the click of the button also means a higher volume of applicants of which a large percentage is unsuitable This also increases the number of candidates clicking without reading a job profile properly, meaning a hiring that isn't carefully scrutinized could result in a negative impact on a hiring manager's time. Whether you use an internal or external recruitment specialist, the need for personal engagement is still vital and will never go away.

The last thing that is notable—particularly for Asia—is that product pipelines for talent and internal development opportunities in every Pharma & Life Sciences business is plentiful, meaning that there is always a huge lack of "push factor" to look externally for competitive opportunities. So, it is imperative that hiring managers and recruiters market their roles to align with the long-term goals and motivations for target candidates, which is key to making a successful and competent hire. Secondly, being proactive towards the passive talent market and playing on the "what's in this role for me?" factors, such as larger scope, better pay, upgrade in job title, and most importantly, the meaningfulness of the product remain critically important.

VOS: **What should we anticipate from the workplace environment for the next 3-5 years?**
PK: The remote working model has most definitely benefited regions like Asia Pacific and has increased our ability to hire previously scarce mid-level HEOR skill sets by allowing candidates to work remotely. However, I do anticipate and have started to witness a shift back to a more hybrid 60% to 80% office-based model due to the increasing need for social and collaborative interactions and information sharing. Most importantly, being present and visible to key internal and external stakeholders has an impact on career advancement.

The HEOR and Partnerships mandate now requires invaluable in-person contact with the stakeholders on the ground, whether a client or internal stakeholder (such as general manager or commercial lead) in countries like China, Korea, Taiwan, or emerging markets where government contact is crucial to ensuring the pharmaceutical or device is meeting all aspects of the public health need. We are no longer an industry where endless modeling skills are enough—there needs to be an infinite stakeholder engagement capability, which is quite unique and rare in this region.

VOS: **How will HEOR work be done in the future?**
PK: Speaking only for my knowledge in Asia Pacific, I see an increase in HEOR demand—not just from vendors but also from internal teams—as the top 10 companies are prioritizing the transition from an "access and pricing" strategy to more transformative "evidence and health economics and outcomes-based value" of product demonstration.

With the commercial activities moving towards a strong partnership with local healthcare ecosytems, HEOR work is likely to be more data-driven and evidence-based in the future. This will involve the use of predictive analytics, artificial intelligence, and machine learning to identify and analyze data from multiple sources. Additionally, HEOR work will become increasingly digital, with the use of cloud-based tools and platforms to store, analyze, and share data. From a career standpoint, HEOR professionals will likely focus more on outcomes research, patient-centered research, real-world data sources, and cost-effectiveness analysis to demonstrate the value of products to payers and other stakeholders.

VOS: **In remote and hybrid models, how can we build leadership succession planning and recruit new employees?**
PK: As an existing leader in a business or organizational perspective (whether remote, fully office-based, or hybrid settings), social interaction is the key to team development. By making the time to be visible within your organization, you can learn so much from hearing your colleagues in a nondirect interaction. Most importantly, the social capital of being present with your team—investing in interactive learning, delegating responsibilities to empower your staff, and sharing your management training and responsibilities while creating a psychological safe space to grow—will allow you to identify high-potential leaders from the outset and develop your teams' strengths and weaknesses.

It's also important to give your team the opportunity to train new members and develop their leadership style early with mentorships. New employees should be able to identify their career paths from day 1.

Again, speaking only from my knowledge and experience around needs in Asia Pacific, more needs to be done to bring

entry-level development into the mid-management level. When hiring new employees, there is too much emphasis in the region on meeting all of the desired skill sets. The industry needs to develop people with potential and on-the-job training; however, due to the existing industry demand and workload, organizations need "plug and play" hires with experience, resulting in roles being left empty for 10-12 months or longer.

In addition, most of the market access and HEOR roles in the industry are still top-heavy, meaning that the roles are primarily occupied by very senior strategic-level people and not filled by people at the much-needed (specifically, in Asia) operational level. Because individual contributors don't manage staff and cross-functional managers support other functions, there are no development structures for these roles—employees can't move up the career ladder and there are no people below them to move into their roles. Therefore, the industry still relies on pharma's top 10 device and healthcare consulting firms—organizations with a developed structure—to develop the talent pools from manager level upwards.

> I see an increase in HEOR demand as the top 10 companies are prioritizing the transition from an "access and pricing" strategy to more transformative "evidence and health economics and outcomes-based value" of product demonstration.

From consulting and vendor perspectives, they have a unique opportunity to bring more international talent into their Asia Pacific headquarters from developed and over-saturated regions such as Europe to train and develop local talent and inspire them to be HEOR and real-world evidence consultants.

VOS: **Which cutting-edge technologies are combined to create a brand-new workplace?**
PK: The future is looking towards artificial intelligence, which can be used to create more efficient workflows, automate mundane tasks, and access data quickly and accurately. Virtual conferencing and work platforms can be used to create an immersive work environment, allowing employees to interact with their environment in a more engaging way.

Longer-term technologies are looking at augmented reality to add digital elements to the physical workspace, allowing employees to visualize data and collaborate with each other in new ways, moving into wearables to track employee performance, allowing employers to gain insights into their performance and make necessary changes. It is an extremely futuristic forecast but ultimately where technology is taking us.

VOS: **In light of all these developments, what qualities do recruiters in the HEOR field value?**
PK: The primary skills have moved significantly away from pure play-modeling technical ability. The HEOR professional requires significant ability with stakeholder engagement and must be able to demonstrate their value, which includes having the credentials and experience in the health technology assessment marketplace when looking for roes in Asia Pacific.

VOS: **How is global hiring currently going and what are the difficulties you're facing?**
PK: Global hiring is becoming increasingly popular as organizations become more interconnected and not restricted by locality. Companies are able to diversify their talent pools and access the best talent from around the world. I recently built a health economics and market access team that had people based in Malaysia, Singapore, Hong Kong, and as far away as New Zealand.
However, global hiring can also bring some challenges. The main difficulties include navigating legal and regulatory requirements; recruiting across different time zones and languages; managing cultural differences; and providing the necessary support and training. Additionally, there can be challenges in establishing reliable remote working processes and managing remote teams effectively.

VOS: **Can you discuss the importance of soft skills in the HEOR field?**
PK: Engagement ability is the #1 skill that is increasingly crucial to demonstrate in interviews. Hiring managers are also looking for strong emotional intelligence, alongside the technical skills we mentioned before. On both the industry side and in healthcare consulting, managing clients and stakeholders means that you can demonstrate the value as an enabling function effectively and perform well across all areas of your engagement chain.

Health economics is an extremely technical field. So, the unique ability to combine presentation connectivity and emotional intelligence with the highly technical modeling and research skills will be in high demand and may be difficult to find.

> Engagement ability is the #1 skill set that increasingly crucial to demonstrate in interviews. Hiring managers are also looking for strong emotional intelligence.

VOS: **What are the anticipated trends for recruitment for 2023?**
PK: We have started to see a strong demand for evidence-focused transformations from global to affiliate countries with more focus on real-world data capabilities. More and more, the priority is bringing evidence-based strategies into the local and medical affairs functions, and the commercial role being transformed in the healthcare and patient partnership. A strong focus for all multinational and top 10 pharma companies is without a doubt: **partnerships, evidence, advocacy, public health,** and **preventive care**. So, commercial activities have to focus on end-to-end engagement through the healthcare and patient ecosystems.

The more traditional health economics, market access, and pricing positions around building regional strategies and commercial launches are likely to be a growing hiring trend in diagnostics, biotech, and devices.

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