White Paper

Health Technology Assessment of Medical Devices in India: Key Considerations for Value Assessment Frameworks

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Prepared by IQVIA in collaboration with APACMed.

FOREWORD

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There has been marked improvement in both economic growth and health standards globally over the past few years. However, the correlation between economic growth and improved health outcomes is unclear and remains complex. Urgent attention needs to be given to the fact that out-of-pocket expenditure constitutes an alarming 60% of the total health expenditure in India. Dedicated efforts and investment, not just in terms of gross domestic product (GDP) but also tangible progress in research and innovation, are required to restructure the fragmented healthcare system in our country.

A very valuable step in this direction is the establishment of health technology assessment (HTA) in India. It is an important policy reform that can assist in identifying unmet health priorities, to ensure the enhanced patient access essential to achieve Universal Health Coverage. This paper highlights the need for integrating different aspects of value by adopting the approach of value-based healthcare in decision-making mechanisms, to achieve desired results. It provides insights on the importance of acknowledging innate differences in the technology being assessed in discussion with stakeholders. These discussions and evidence-based information can help apprise healthcare policies and priorities that require investment to promote an equitable, efficient, high-quality health system.

It is in this context that APACMed and IQVIA partnered to undertake this review, which is an extension to our regional white paper on the same subject. This review maps the current landscape, regional best practices, and role of the medical devices industry in HTA in the Indian context. Lastly, certain recommendations have been made on the way forward through collaborative efforts, to ensure a holistic HTA ecosystem that can withstand all possible odds in the years to come.

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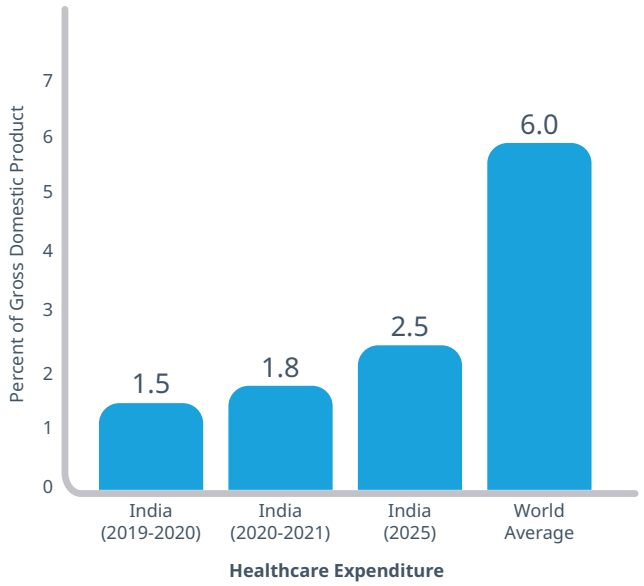
Current landscape

HEALTHCARE EXPENDITURE IN INDIA

Over the last two to three decades, India – along with its peers in South Asia – has witnessed tremendous economic growth. However, the correlation between economic growth and better health outcomes is complex and unclear.[1] India's public health expenditure is lower than the world average (figure 1), even when compared to Brazil, Russia, India, China, and South Africa (BRICS).[2] It is one of the lowest, even among developing countries.[3,4] This leads to extensive out-of-pocket expenditure, which accounts for 63% of the total health expenditure, as per a 2018 World Health Organization (WHO) report.[5] However, the National Health Policy 2017 has envisaged increasing healthcare expenditure to 2.5 % of the gross domestic product (GDP) in the coming years.[6] To meet this commitment, the Government of India has taken a step in the right direction by increasing healthcare expenditure to 1.8% of GDP under the 2021 budget (Figure 1).[7]

Figure 1: Current and projected healthcare expenditure in India in comparison to world average



NEED FOR HEALTH TECHNOLOGY ASSESSMENT

Despite the limited healthcare budget, in line with the WHO's directive, India has taken up the task of achieving universal health coverage (UHC) by 2030 with upmost priority. To achieve this goal, it is paramount to have efficient health systems, trained healthcare workers, and easy access to medicines and technologies while ensuring affordability of treatment options.[8] Globally, health technology assessment (HTA) is one of the tools used to inform the value of health technologies such as medicines, medical devices, vaccines, procedures, and healthcare systems, and helps their integration within UHC when needed. In India, the implementation of public-financed universal health insurance schemes, such as Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB–PMJAY) (a tax funded health insurance scheme that aims to provide a coverage of INR 500,000 to over 100 million vulnerable families for secondary and tertiary care services at public and private facilities), has several medical devices as part of select health benefit packages. This has further increased the need for a comprehensive evaluation of medical devices for funding-related decisions.[9]

> HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.
>
> International task group led by International Network of Agencies for HTA (INAHTA) and HTAin

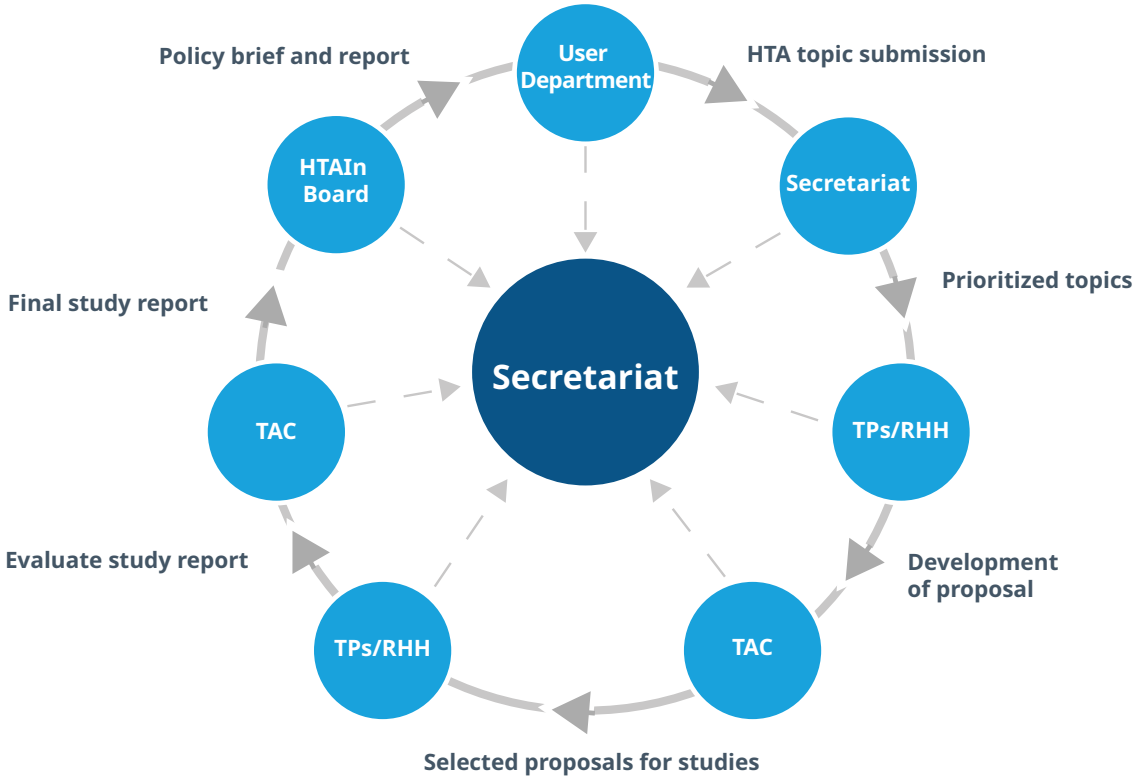
Recognising the role of HTA in evidence-informed decision-making in healthcare and in alignment with the objective to provide UHC, in 2017, the Government of India set up HTA India (HTAIn), the official HTA centre under the Department of Health Research, Ministry of Health and Family Welfare.

HEALTH TECHNOLOGY ASSESSMENT FRAMEWORK IN INDIA

Subsequent to its setup in 2017, in 2019, the draft HTA Board Bill was introduced to constitute an act directed to institutionalise the structure and functioning of the HTAIn body.[10] The draft Bill was placed in the public domain for stakeholder inputs, and it is currently under consideration by the Department of Health Research.

HTAIn is comprised of five core bodies – the Secretariat, the Technical Appraisal Committee (TAC), Regional Resource Hubs (RRH), Technical Partners (TPs), and the HTAIn Board.[11] Currently in India, the request for an HTA study can be submitted by any government healthcare provider or agency involved in healthcare or the central or state health ministry (user departments) to the Secretariat for evaluation. The Secretariat can also initiate topics for HTA.[11,12] The stepwise HTA process in India is shown in Figure 2.

Figure 2: Stepwise HTA process in India



Abbreviations: TAC, Technical Appraisal Committee; TPs, Technical Partners; RRH, Regional Resource Hubs, HTA, Health Technology Assessment; HTAIn, HTA India.

HEALTH TECHNOLOGY ASSESSMENT STUDIES IN INDIA

Since the inception of HTA in India, about twenty studies assessing the economic implications of different procedures and pharmacologic interventions using cost estimates from public healthcare facilities have been submitted. To date, eleven studies have been completed, of which ten are focused on medical devices,[13,14] with applications ranging from diagnostic screening and therapeutic care to surgical use. The positive impact of a few studies is evident, as their recommendations have been adopted as policies. Clinical use of safety-engineered syringes (SES) is now mandatory in Punjab, Andhra Pradesh; other states are set to implement this policy.[15–17] While the diverse studies undertaken by HTAIn are commendable, especially given the limited availability of resources, the inherent challenges faced should be looked at closely to drive better outcomes in the future.

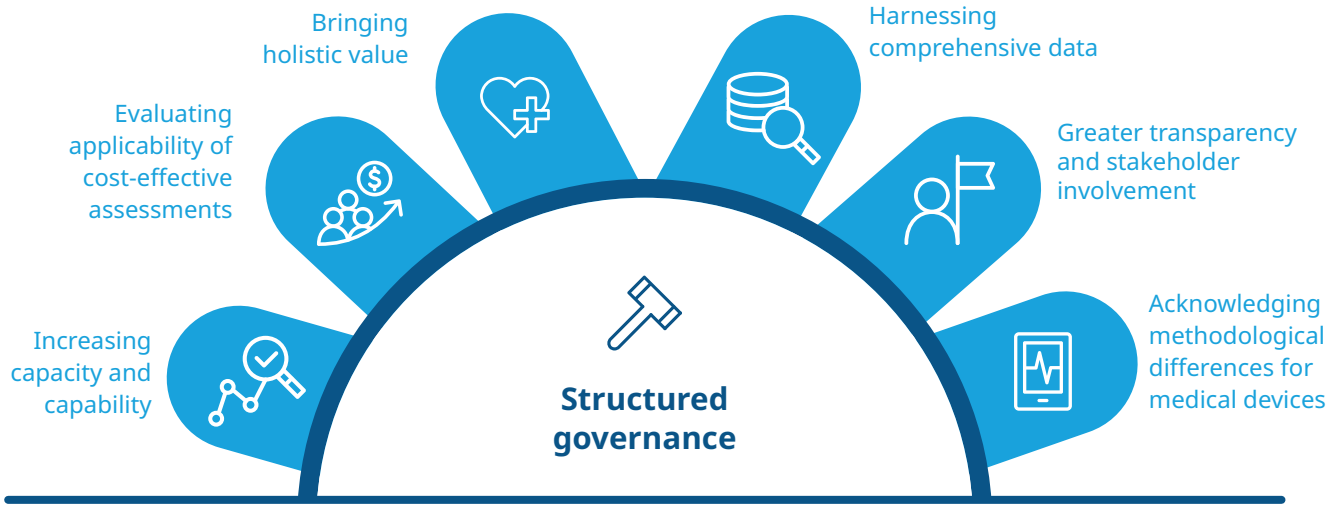
Case study: Safety-engineered syringes (SES) in Punjab, India[16]

In India, over 63% of injections are reportedly unsafe or deemed unnecessary. Unsafe injection practices lead to the spread of blood-borne infections, making it important to address this public health concern. In the evaluation process, three types of SES were evaluated; reuse preventions syringe (RUP), sharp injury prevention syringe (SIP), and RUP+SIP combination. The data analysis showed that the introduction of SES can bring down a total of 96,269 hepatitis B, 44,082 hepatitis C, and 5632 HIV deaths. As per the cost-effective model, RUP syringes are more cost-saving than SIP and RUP+SP, at the Punjab state level, with an incremental cost of INR 28,668 (US$441) per QALY gained; there is a 96.5% probability of RUP becoming cost-effective with annual treatment cost savings of about INR 62.5 million (US$0.96 million), based on the results of the study. The State of Punjab adopted RUP syringes as a policy within their injection safety program for therapeutic care in both the public and private sectors.

KEY CONSIDERATIONS FOR HTA IN INDIA

To standardize and streamline processes, and promote transparency in decision-making, paying a greater attention to the following key aspects is crucial (Figure3)

Figure 3: Key areas of consideration for HTA in India



INCREASING CAPACITY AND CAPABILITIES

In India, HTA is in a relatively nascent stage, with existing gaps in capabilities and evolving skillsets, making it challenging to ensure the required technical rigour, consistency, and quality for successful adoption of HTA are available.[18] In view of inadequate budgetary allocation, identifying unmet health needs and prioritising these immediate needs should be the practical and focal point of HTAIn at this moment. In addition, HTAIn should consider increasing the number of experts who can carry out the required analyses and building focused educational programmes to instil the required skills in them.[19] The utilisation of currently established resources to their full potential is also essential for the continued successful implementation of the HTA framework.

HTAIn is steadily working on these priorities to develop scientific expertise by engaging with the International Decision Support Initiative (iDSI) and institutes such as Tata Institute of Social Sciences (TISS).[19–21] This collaboration aims to strengthen and support evidence-based decision-making to develop health policies and improve access to high-quality health services. Other steps have already been undertaken to improve capabilities, viz. the development of various detailed guidance documents (process manual, reference case, and detailed methods manual) and policies (conflict of interest policy).[11,14]

EVALUATING THE APPLICABILITY OF COST-EFFECTIVENESS ASSESSMENTS

The cost-effectiveness threshold (CET) concept represents the highest value that a society is willing to pay (WTP) for an intervention;[22] however, in India, the current WTP is a suggested threshold of the per capita gross domestic product per year of life saved.[23,24] Evidence supporting these suggested thresholds is still unclear. There is a paucity of quality cost data, which compounds this problem.[25–27] Unless the healthcare budget is increased to match global benchmarks, cost-effectiveness will only drive willingness to pay to extremely low levels. A lower threshold can deter industry investment in India from a global perspective. Also, an explicit threshold in countries with high medical and financial unmet needs, such as India, could be viewed as a price-capping mechanism to ration care.[28,29]

> CET cannot be a decision rule, rather it should be the guiding principle for aiding decisions.
>
> Prinja et al.

Price control can affect future investments in research and development activities, thereby limiting innovation.[47] Such a system will promote the development of high-cost innovative technologies by hindering incremental innovations in highly competitive areas.[46]

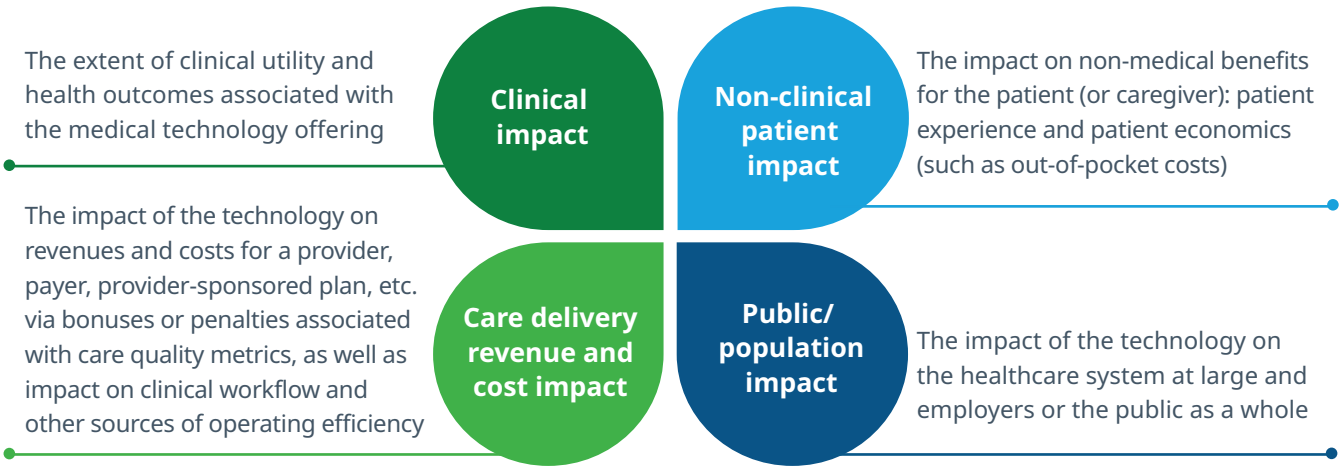
While current assessment parameters might be appropriate for interventions directly impacting clinical outcomes (i.e., pharmaceuticals), they should not be adopted from the perspective of “one size fits all”, especially when it comes to medical devices, which go beyond the traditional measurement matrix. The WHO suggests that the fixed cost-effectiveness threshold should never be used as a standalone criterion for decision-making.[29] There has been growing interest in utilising the principles of value-based healthcare (VBHC) as an alternative tool for decision-making that could be incorporated into HTA systems.

BRINGING HOLISTIC VALUE

Globally, the healthcare delivery model is shifting from a volume-driven care, i.e. fee-for-service, model, to a VBHC model that emphasises patient outcomes and quality. This shift drives MedTech and pharma companies to develop and expand innovative treatment modalities, delivery systems, and payment models.[30, 31]

HTA decisions pertaining to technology should reflect broad views of value, as assessed from multiple stakeholders' perspectives and over the entire care continuum. In addition to clinical and economic evidence, value assessments should consider the following: efficiencies delivered, level of unmet need, public health priorities, disease severity, caregiver burden, stakeholder expert input (especially patients and physicians), and level of innovation (Figure 4).[32,33] HTA processes should be deliberative, flexible, and balanced between quantitative and qualitative evidence, instead of adopting a fully quantitative approach, for continued innovation. Value assessment should be comprehensive and inclusive of all elements of value relevant to the given jurisdiction. Value has different meanings to all parties involved in healthcare and should be viewed through an individual lens, not just health outcomes achieved per rupee spent. Therefore, decisions based on HTA evaluation should take a holistic perspective of value, comprehensively considering how patients feel, function, and survive, as well as the broader context within which technology will influence practice.

Figure 4: Four broad categories of value[33]



HARNESSING COMPREHENSIVE DATA

In a vast country such as India, the generation of and access to healthcare data poses a big challenge. Therefore, even though the studies completed thus far are quite comprehensive, their national representability and generalisability become questionable.[25] The Indian National Cost database aims to address this challenge for the public sector. It provides a single source of costing information for healthcare policymaking from 16 different states in India.[34] To fill this gap for the private sector, increased payer/provider collaboration, collecting real cost data, sharing of patients' health data, and information technology (IT) and analytical support are needed.[30,31] The availability of newer technologies, such as health apps, remote monitoring, and software as a medical device are giving access to previously inaccessible data – bringing patient care to the home, increasing patient engagement, and enabling us to think beyond the traditional marker of cost. With the advancement of technology, the relative ease of acquiring claims databases from state-owned and private insurance companies will go a long way towards ensuring the availability of data for analysis as well.[35] The recent establishment of the National Digital Health Mission (NDHM), which aims to develop the backbone necessary to support the integrated digital health infrastructure of the country, is a step in the right direction. VBHC will make manufacturers share performance and outcomes data with providers and help accelerate patient access to technologies that can demonstrate improved value and outcomes.

ACKNOWLEDGING METHODOLOGICAL DIFFERENCES FOR MEDICAL DEVICES

HTA methodologies and decisions should be appropriate for the device or technology in question, taking into consideration the heterogeneity of medical technologies available. Assessment methodologies should be appropriate to the technology being evaluated, allowing for pragmatic adaption when required. For medical device HTA, it is critical to judge value not only based on clinical outcomes but also on impact; consideration must be given to the entire chain of healthcare delivery.[36] Medical devices could have multiple applications, and evidence generated from HTA on one indication or use cannot be generalised for other indications. The challenge of determining the monetary impact of the "learning curve" and incorporation of small incremental innovations for improved outcomes must be acknowledged for medical device HTA. Furthermore, medical device HTA decision-making may be more complex compared to that of pharmaceuticals due to inherent differences in use and outcomes (Table 1).

Table 1: Considerations to be accounted for medical device HTAs

CHARACTERISTIC	CONSIDERATIONS FOR MEDICAL DEVICES
OUTCOME DIFFERENCES	• Diagnostic versus therapeutic outcome • Long and complex causal pathway to health outcomes
LEARNING CURVE	• The effectiveness in performance of the device heavily relies on the skill and experience of the operator
ORGANIZATIONAL DIFFERENCES	• Devices benefit from system redesign or shift in settings • Help in shortening healthcare time throughput by making healthcare delivery efficient
USABILITY DIFFERENCES	• User preference and ability to use a particular device
COST OF DELIVERY	• Consideration of per-patient planning and delivery cost in addition to cost of the device • Some medical devices are large-capital equipment; the cost distribution across different areas of application needs consideration
PACE OF INNOVATION	• Rapid pace of innovation
CLINICAL EVIDENCE	• Difficult to perform blinded randomized clinical studies • In some cases, it might be unethical to perform sham procedures
APPLICABILITY	• Medical devices can be used across range of interventions and indications • Evidence from HTA may not be generalizable to all other areas of application
DEVELOPMENTAL STAGE	• HTA in early-stage development may have less positive results compared toassessments done at a later stage following upgradation of device, based on user experience and skills
PRICE DIFFERENCES	• To consider the rapid competition and competitive pricing for medical devices while avoiding perverse incentives
PRODUCT LIFECYCLE	• Shorter developmental cycle and faster incremental chances

The entire chain of healthcare delivery implementation must be considered, not just the sensitivity and specificity of the medical device.

GREATER TRANSPARENCY AND STAKEHOLDER INVOLVEMENT IN HTA PROCESS

In India, siloed decision-making processes and heavy reliance on expert opinion – along with the complex healthcare governance structure – make it difficult to transcend the applicability of HTA processes beyond academia.[37–39] HTA agencies should identify and apply best-practice approaches to evaluate, assess, and disseminate the outcomes of technology assessments, as well as monitoring the recommendations of their appraisals in a transparent manner.[40] A list of technologies proposed for review should be made publicly available, with active solicitation of broader stakeholder engagement. The processes and timelines for this engagement should be transparent, and the methodology and assessment outcomes should be made available for review and comment. The stakeholder engagement should be broadened to include patients, patient advocacy groups, caregivers, clinicians, providers, payers, and industry. All stakeholders should have the opportunity to actively participate in all relevant steps of the HTA process (Figure 5), with opportunities for early industry consultation for horizon technologies. The HTA process should be efficient and appropriate, with due consideration given to the timeliness of technology assessment. Expedited review timelines, processes, and methodologies should be applied for technologies addressing priority patient unmet needs. The process should also include an opportunity for appeal to resolve any disputes.

Figure 5: Roles of stakeholders in HTA

Abbreviations: TAC, Technical Appraisal Committee; TPs, Technical Partners; RRH, Regional Resource Hubs; HTAIn, HTA India.

IMPROVED MEDTECH INDUSTRY ENGAGEMENT IN HTA

As manufacturers and innovators of medical technologies, the MedTech industry has a lot to offer and is an integral part of the HTA process. The industry not only provides access to a wealth of evidence they collect for a technology through its lifecycle, but it can also advise based on its understanding of different markets and/or other similar technologies. As India moves towards establishing and solidifying its HTA system, it should assess and leverage the benefits of industry involvement.

Globally, the role of industry in the HTA process varies across countries – depending on local social, cultural, and economic factors. The industry's role in HTA varies from being an applicant, reviewer, strong collaborator to not being involved at all. India may focus on a more structured and institutionalised industry with opportunities to collaborate and actively participate in all the relevant steps of the HTA process. An example of such a collaborative model is evident from how the Health Information and Quality Authority (HIQA) in Ireland and the National Institute for Health and Care Excellence (NICE) in the UK function. These agencies have successfully leveraged scientific knowledge and expertise of all key stakeholders to develop guidelines and models for evaluation of health technology in their respective countries.[41,42]

STRUCTURED GOVERNANCE

HTA agencies should have a clear mandate, governance structure, and accountability frameworks[43] to establish a clear understanding of the HTA agency's purpose, structure, and objectives. Where HTA is used to inform decision-making, a transparent governance structure provides clarity on the roles and responsibilities of the agency and clearly defines the relevant groups to which it is accountable. This ensures that individuals and committees act according to their mandated objectives; can be held accountable to transparent decision-making; and are using their expertise and resources on behalf of the best interests of those to whom they are accountable – free from conflicts of interest.

Recommendations for the road ahead

Establishment of HTA within the vast and complex Indian health system is a significant step towards meeting the goal of universal healthcare. Increased healthcare spending, along with the appropriate implementation of an HTA system guided by the principles of VBHC, can bring about maximisation of health and reduce inequalities in access to healthcare.[44,45]

SHORT TERM

Encouraging Innovation

One way in which governments, HTA bodies, and healthcare decision-makers can encourage the development of innovative health technologies is by recognizing and rewarding innovation, irrespective of the country of origin.[46, 47] As we experience rapid innovation, our evaluation methodologies need to also evolve to be more pragmatic and adaptive to accommodate future novel technologies. HTA agencies will be challenged with assessing products without comparators and are rapidly evolving with short life cycles, making current assessment methodologies and evidence generation difficult and impractical. Thus, to promote innovation, a balance is required between identifying the value of the type and level of innovation and its impact on health outcomes, while addressing overall accessibility and affordability.

Setting Up Priorities

Considering budgetary constraints, HTA in India should act as a systematic policy tool for prioritising and identifying interventions that can be included in government schemes. When effectively used, HTA can act as a tool for negotiating increased budget allocation, especially in line with the goal of increasing healthcare allocation in the coming years.[29] HTA is not a price-containment tool to achieve UHC, but rather a tool to inform policy and funding decisions. Thus, identifying healthcare priorities that can be covered with a limited budget needs to be the focus, rather than the expectation of any intervention to meet a set threshold.

Establishing Processes

HTAIn may benefit from the development of processes that focus on identifying and prioritising unmet health needs and determining how to best address these needs. Establishing stepwise processes to track the implementation and outcomes of approved HTAs over time will help HTAIn and stakeholders to identify gaps and ensure that necessary steps are undertaken regarding the current HTA framework for future assessments. To bring legitimacy and credibility to HTA, open participation, accountability, high technical rigour, and transparency of methods, data, and decision-making will be crucial.

Collaborative Approach

In culturally and socioeconomically diverse countries such as India, collaboration plays a vital role in leveraging technology and resources to fulfil healthcare needs. Ensuring multi-representative stakeholder involvement and joining forces with industry for a comprehensive evaluation to fulfil the ultimate goal of affordable, quality healthcare are key steps in the right direction. A key attribute of HTA maturity is transparency. Evolving HTA agencies should consider adding greater transparency in the submission process, stakeholder engagement, and evaluation methods to evolve rapidly through the HTA maturity curve.[48]

LONG TERM

Value-Based Healthcare

The future should see the implementation of a more pragmatic VBHC framework that is inclusive of holistic measurement of costs and associated consequences. An approach that is supported by local legislations, includes stakeholder inputs, and is fair and transparent needs to be developed to increase accountability in decision-making.[49] These challenges and considerations should be thought out with innovative funding mechanisms such as Coverage with Evidence Development, a programme established by the Centers for Medicare and Medicaid in the United States.[50] Such programmes can be beneficial for all stakeholders involved, especially the clinical and patient communities, as they are based on the fulfilment of established criteria. These programmes allow access to newer technologies and help in the generation of the required real-world clinical evidence.[51] VBHC will create a balance between identifying the value of the technology and assessing technology's impact on health outcomes, while addressing overall accessibility and affordability.

By implementing good governance independent of conflict of interest and incorporating flexibility, scalability, capacity-building, greater transparency around decision-making, strong collaborative stakeholder engagement and rigorous quality monitoring, India can achieve its vision of a strong, holistic HTA system.

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Kiran is a Senior consultant with IQVIA's Health Economics and Outcomes Research (HEOR) team. In her current role, Kiran manages and delivers various projects related to HEOR, Real World Evidence and HTA across different geographies.

With over 10 years in healthcare, she has a wide array of experience in research management within both academic and industry-sponsored research programs. She specializes in clinical research administration, research operations, scientific writing, and regulatory compliance. Her strong commitment to research and wide array of experience has given her the opportunity to impact patient health.

Prior to joining IQVIA, she led and managed all phases of national and local level research studies within multiple therapeutic areas in India and the USA. Kiran is a pharmacist by training and holds a Master's degree in Clinical Research from Eastern Michigan University, USA.

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Tomoghana is a Senior consultant with IQVIA's Health Economics and Outcomes Research (HEOR) team. In his current role, he is supporting in writing and designing various observational studies, database studies, and HEOR related projects with a wide array of teams and healthcare organizations. In his 15-year career in medical writing, he has worked on all types regulatory writing documents along with various scientific articles. His writing domain encompasses all therapeutic areas and he has worked extensively on both interventional and non-interventional trials. Tomoghana is a pharmacist by training and holds a Master's degree in pharmacology.

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Harjit was appointed CEO of APACMed in February 2019. She was formerly EVP and CEO of Philips ASEAN & Pacific until October 2015. In this role, she managed a team of 10,000 people in 10 countries across its Healthcare, Lighting and Consumer Lifestyle sectors. Harjit spent over two decades with Philips holding a variety of international roles in General Management in England, Holland, Singapore, Dubai and Hong Kong. Passionate about innovation and healthcare reform, she holds concurrent positions on several prestigious boards including ResMed, MAS Holdings, Apollo Education, Delmedica, Harjit has spoken at several global leadership platforms including the World Economic Forum, INSEAD and IMC on Innovation and Healthcare.

ANIRUDH SEN
Country Lead, India, APACMed

Anirudh joined APACMed as Country Lead for India in May 2020, with an objective to enhance APACMed's footprint and engagement in the country, and lead APACMed's cross-functionally through Government Affairs, Market Access, Regulatory Affairs, Digital Health and Legal/Ethics/Compliance initiatives in India. He has eighteen years of diversified work experience with expertise in policy advocacy, government relations, research and analysis, stakeholder management, content management, business events and marcom. Prior to joining APACMed, Anirudh was working in the Health Services, Medical Value Travel, Medical Devices and Health Insurance sectors at the Federation of Indian Chambers of Commerce and Industry (FICCI), driving policy initiatives that facilitate in ease of doing business, enhance efficiency, global competitiveness and expanding business opportunities for the industry.

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About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of information, innovative technology solutions and contract research services focused on using data and science to help healthcare clients find better solutions for their patients. Formed through the merger of IMS Health and Quintiles, IQVIA offers a broad range of solutions that harness advances in healthcare information, technology, analytics and human ingenuity to drive healthcare forward. IQVIA enables companies to rethink approaches to clinical development and commercialization, innovate with confidence as well as accelerate meaningful healthcare outcomes. IQVIA has approximately 55,000 employees in more than 100 countries, all committed to making the potential of human data science a reality. IQVIA's approach to human data science is powered by the IQVIA CORE™, driving unique actionable insights at the intersection of big data, transformative technology and analytics with extensive domain expertise.

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About APACMed

A unified voice for MedTech companies, coming together to improve standards of care and strengthen healthcare systems across Asia Pacific.

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific, representing both multinational corporations as well as small and medium enterprises, together with several local industry associations across the region.

Headquartered in Singapore, APACMed's mission is patient-centric, and we strive to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific. We are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

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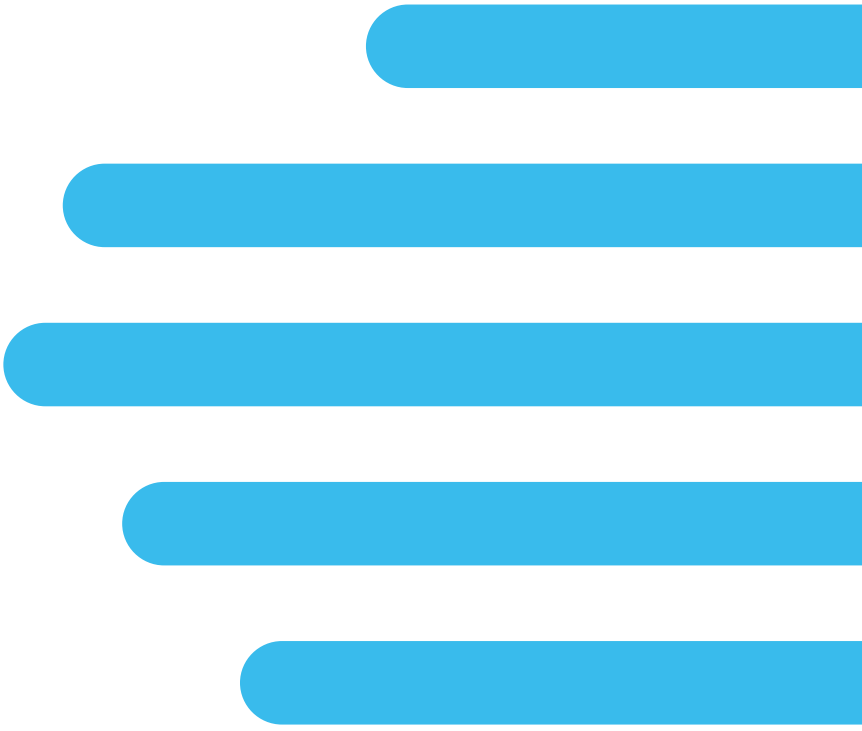

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