



The voice of MedTech

Moving towards a value-driving medical technology assessment: A multi-stakeholder perspective

Public Policy and Market Access Summit
Asia Pacific Medical Technology Association
(APACMed) MedTech Forum 2019



Introduction to the Summit



APACMed held its first Public Policy and Market Access Summit at the MedTech Forum on 9th October 2019. This summit was timely, given the backdrop of a rapidly changing healthcare ecosystem driven by demographic and epidemiological shifts across the Asia Pacific (APAC) region. These changes have contributed to rising healthcare costs and subsequent impacts on patient access to medical technologies. Consequently, there is a growing interest in establishing different methods of assessing medical technologies to inform policy, pricing and reimbursement decision-making.

The purpose of this summit was to:



The summit opened with an introduction to APACMed, and the Public Policy and Market Access Summit by **Ms Shakilla Shahjihan** (Chair, Government Affairs Committee, APACMed) and **Ms Georgia Swan** (Manager, Government Affairs, APACMed). This was followed by insights into the challenges and opportunities in value assessment for medical technologies, presented by experts in the field: **Ms Miyeong Kim** (Representative of the Korean Society of Type 1 Diabetes), **Mr Markus Siebert** (Senior Director, Health Economics & Reimbursement, Abbott), **Ms Sirinthip Petcharapiruch** (Principal, Real World Solutions, IQVIA APAC) and **Professor Jianwei Xuan** (Professor & Director, Sun Yatsen University). After which, **Professor Stephen Goodall** (Deputy Director, Centre for Health Economics Research and Evaluation), **Professor Ataru Igarashi** (Associate Professor, Unit of Public Health and Preventive Medicine, School of Medicine, Yokohama City University), and **Dr Mingdong Zhang** (Chief Medical Officer & Vice President of Strategic Medical Affairs, Boston Scientific Asia Pacific) presented on topics related to HTA evaluation of medical technologies from the perspective of various countries and their real-world application. The summit concluded with a panel discussion with Mr Siebert, Ms Petcharapiruch, Professor Xuan, Professor Goodall, Professor Igarashi and Dr Zhang, moderated by **Dr Yan (Viva) Ma** (Outcomes Research Lead HEOR Centre of Excellence, Greater Asia Becton Dickinson).

Key Challenges in Assessing Value

Value is a Multidimensional Concept

Mr Siebert outlined key challenges including the **existence of multiple stakeholders** within the health system, such as clinicians, payers, and patients, with differing definitions of value. Value incorporates clinical, economic, patient and societal aspects, all of which are prioritised differently by the various stakeholders within the health system. Thus, defining value becomes challenging due to **its subjective and context-specific nature**. Furthermore, **a lack of established metrics for assessing value holistically** makes it difficult to align the different definitions of value across multiple stakeholders. Currently available metrics for measuring value are mainly established to define clinical value.

Professor Xuan also reiterated the multiple dimensions of value in his presentation and noted that the value of a medical technology is often defined from the government's perspective due to current healthcare reimbursement policies. **There is a focus on elucidating value from the clinical and economic dimensions, which can undermine the true value of these technologies.** As an example, Professor Xuan shared findings from his research evaluating the value of imported versus domestic surgical staplers. Findings point to an emphasis on using unit price to make reimbursement decisions in the Chinese healthcare system, which may be counterproductive if other aspects of value are not considered.

Value from a Patient Perspective is often not Incorporated

Patients are often not consulted nor engaged with appropriately in the decision-making process. Yet, patient engagement is a vital component of developing patient-centred healthcare policies, to ensure that value to patients is well-captured in policy decisions. Ms Kim shared her journey as a patient advocate for type 1 diabetes (T1D) in Korea. Having identified an unmet need for continuous glucose monitoring (CGM) for T1D patients in South Korea, she approached various stakeholders within the health system to advocate for the reimbursement of CGM in South Korea. Due to the lack of adequate patient engagement in the reimbursement decision-making process, Ms Kim faced various challenges, including with regulatory bodies, before she finally successfully obtained reimbursement of CGM in South Korea.



Methods for Assessing Value are not Established in Asia Pacific

Within the APAC region, there has been a growing interest in the application of health technology assessment (HTA) to evaluate the value of medical technologies to inform pricing and reimbursement decisions. HTA is a systematic approach to evaluating medical technologies, combining concepts from multiple disciplines. Ms Petcharapiruch noted that **the current HTA landscape within APAC is very heterogenous**. HTA systems across the spectrum of development exist in the APAC region, and most markets within APAC have yet to establish clear processes or guidelines specifically for assessing value of medical technologies.

Differences between Pharmaceuticals and Medical Technologies

Differences in Evaluation Criteria

In health systems where HTA is commonly used for reimbursement decisions in healthcare, evaluation criteria often differ for pharmaceuticals and medical technologies. Ms Petcharapiruch and Professor Goodall noted that this is due to differences in application and innovation when comparing both product types. **HTA guidelines and processes for medical technologies tend to be less developed** when compared with those for pharmaceutical reimbursement. This is in part due to the short life cycles and multiple changes involved in the product development process for medical technologies. Additionally, the efficacy of a medical technology not only depends on the device itself, but also how it is used – there may be a need for skilled personnel to implant or administer such technology. Robust data are not always easily available to evaluate medical technologies due to the small population size, and equivalent clinical evidence may not be available for all products, making comparisons difficult.

Using ventricular assist devices (VADs) as a case study in Australia, Professor Goodall compared the value of VAD using the evaluation criteria for medical technologies and for life-saving drugs. While VADs met all the criteria as a life-saving product and would be eligible for federal reimbursement under the life-saving program if it were a pharmaceutical drug, VADs were not considered eligible for reimbursement when evaluated against standard HTA criteria for medical technologies in Australia. Given that medical technologies can bring similar value to patients, Professor Goodall concluded that consistent evaluation criteria should be used to evaluate both types of life-saving products.



Differences in Innovation and Incentives

Current HTA processes for medical technologies are also seemingly disconnected from reimbursement outcomes. Mr Siebert noted that medical technology innovations, unlike in the field of pharmaceuticals, tend to be incremental due to the product life cycle, such as improvements in the battery life of a device. While this contributes to an overall increase in the value of the technology, it is not usually acknowledged in terms of market price.

Opportunities for Redefining and Improving HTA for Medical Technologies



Increasing Linkage between HTA for Medical Technologies and Reimbursement

- Enhancing the linkage between value and payment can incentivise the industry to constantly innovate and develop high value products to improve patient outcomes. Professor Igarashi shared that HTA in Japan rewards innovative products through the use of clear guidance and innovative tiering in the HTA process. Medical technologies that are eligible for these tiers are awarded premium prices to acknowledge the value that innovation brings to the health system.



Establishing the value of products to patients and regulators early in the product life cycle

- Identifying and generating appropriate evidence is important in demonstrating the value of a medical technology in terms of clinical, economic and societal impact. Mr Siebert emphasised that manufacturers should actively engage decision-makers, clinicians and patients to better understand what they value in a product so that they can generate the appropriate evidence to define the value of their products.



Considering alternative approaches

- Risk sharing agreements (RSA) facilitate patient access to innovative medical technologies without full evidence of clinical benefit while ensuring budgetary control.
- Multi-criteria decision-making (MCDA) allow for the inclusion of a comprehensive list of value dimensions, assignment of quantitative weights across dimensions and enabling more involvement of relevant stakeholders.
- Real world evidence (RWE) complements traditional clinical data to increase our understanding of the performance of a medical technology in the real-world setting to inform benefit-risk assessments.



Developing frameworks to embrace digitisation

- The evolving landscape of medical technologies towards digitisation highlights the need for reiterative, pragmatic evaluation processes. Dr Zhang shed light on the new 'Software as a Medical Device' (SaMD) framework developed by the Food and Drug Administration (FDA) in the US to evaluate software that are intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device through an automated, reiterative process using smart regulation principles.

Panel Discussion – Moving Towards a Best Practice Framework

In the panel discussion, speakers highlighted the importance of aligning the definition of value across different stakeholders in the HTA process so as to effectively capture the true value of a medical technology to the health system.



Efforts to Take a Holistic Approach to Value

Professor Xuan shared the efforts that Chinese regulatory bodies have taken to **adopt a holistic approach towards evaluating value**. The evaluation criteria for medical technologies are undergoing revisions, and regulatory bodies have incorporated patient and societal values in their evaluation criteria. These guidelines are expected to be piloted in local hospitals in seven provinces soon.

In the context of Japan, Professor Igarashi shared that **patients' perspectives are incorporated in the evaluation process** by involving one committee member from a patient group in the decision-making. However, this representative is the same for different technologies that aim to manage different disease areas. Similarly, in Australia, a patient representative sits on the evaluation committee but is not necessarily a patient with the specific condition for which a product is evaluated. There are opportunities for enhancing the process in which patients' perspectives are actively and adequately incorporated in the defining of value. One method of patient engagement that was discussed was the public consultations that the Australian regulatory bodies conduct to receive feedback on their processes.

Converging Evaluation Criteria for Medical Technologies and Pharmaceuticals

The panel agreed that the value of pharmaceuticals to patients and the health system are not different from that of medical technologies, as they both serve to improve health and manage diseases. Thus, as HTA processes are refined, **the evaluation criteria for both pharmaceuticals and medical technologies should increasingly converge**.

Professor Xuan shared that there are deliberate efforts being made in China to have one regulatory body evaluate both pharmaceuticals and medical technologies. Such efforts include the development of clear HTA guidelines, and ongoing discussions to increase transparency around the criteria used for evaluation, such as the willingness-to-pay threshold used.

Evaluation Criteria will have to Develop over Time

The panel agreed that there is a need for reimbursement processes to be redesigned so that **preventive health technologies can be reimbursed for their true value**, and to support manufacturer innovation and patient access. The Japanese health system is an example of one that does not reimburse preventive health technologies. Professor Igarashi shared that tobacco patches in Japan are reimbursed as a treatment for nicotine addiction, even though they are commonly used as a smoking cessation aid. This is to allow the reimbursement of nicotine patches, which would otherwise not qualify for reimbursement as a preventive health technology.

Regulatory bodies will also need to be receptive of new approaches to evaluating such technologies, especially in situations where traditionally collected clinical evidence is not feasible. This will include the use of RWE, where robust data from traditional clinical studies cannot be obtained, in the consideration of the clinical impact of a technology.

Moving Forward

As healthcare reimbursement models move from being price-based to value-based, HTA processes must be updated to support this. To address the challenges intrinsically linked to evaluating medical technologies, there is a need for clearer guidance on the process of evaluating medical technologies. This will involve establishing clear guidelines on the evaluation process and evidence requirements. Such guidance not only increases transparency around funding criteria, but can also support innovation among the industry, as the link between funding decisions and innovation is made clearer.

There will be opportunities for various stakeholders to reshape the field. Knowledge generated by researchers is crucial to improving HTA processes, and input from providers and patients can help to inform funding decisions. Governmental bodies and manufacturers also play an active role in defining HTA. Manufacturers can undertake this by establishing strong product value propositions early in the product life cycle, by understanding the evidence requirements in each market, and by building partnerships with providers, patients, and decision-makers for sustainable outcomes. APACMed seeks to foster collaboration between industry and all of these stakeholders to help support value-based decision-making and ensure patient access to important medical services.

About APACMed



Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the first and only regional association to provide a unified voice for the medical technology industry across Asia Pacific. The mission of APACMed is to improve patient access to high quality healthcare and life enhancing technologies. APACMed works proactively with bilateral, regional and local government bodies and other healthcare stakeholders to shape policies, foster innovation and promote regulatory harmonisation. APACMed works with medical device associations and companies in Asia Pacific to jointly advance regional issues, codes of ethics and share best practices.

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Speakers



Ms Shakilla Shahjihan

Chair, APACMed Government Affairs Committee

Shakilla Shahjihan is Divisional Vice President, Government Affairs at Abbott based in Singapore. She and her team members across strategic markets in the region lead external stakeholder engagement to help drive business priorities. Shakilla chairs the Women Leaders of Abbott in Singapore and is an elected member of the Board of Governors in AmCham Singapore. She also chairs the Government Affairs Committee of APACMed; and is an active participant in the Management Committee of the Asia Pacific Infant and Young Children Nutrition Association (APIYCNA).



Ms Georgia Swan

Manager, Government Affairs, APACMed

Georgia Swan has experience working in various roles across the Australian health sector in health publishing/media production, medical writing, and health programme design and implementation. Prior to joining APACMed, Georgia worked in healthcare and strategy at Medibank Private, Australia's largest private health insurer, developing and implementing health management solutions for Medibank members.



Ms Miyeong Kim

Representative of the Korean Society of Type 1 Diabetes

Miyeong Kim is a consumer advocate from South Korea, a representative of the Korean Society of Type 1 Diabetes, and a Director at the Korea Alliance of Patients Organisation. Inspired by her son who has type 1 diabetes, she worked with the Government to turn South Korea into a country that now provides reimbursement for CGM for people with type 1 diabetes. Miyeong also holds roles as the Administrative Director of the SugarTree Community and Night Scout Korea Community.



Mr Markus Siebert

Senior Director, Health Economics & Reimbursement, Abbott

Markus Siebert is Senior Director, Health Economics & Reimbursement, International, at Abbott. He is responsible for the development and execution of reimbursement strategies and guides the development of health economics and other evidence to support market access for Abbott medical device innovations in Europe, Asia and Australia. Markus has also held various leadership roles in the field, having been Chair of the Evidence & Payers Working Group at MedTech Europe; Chair of Eucomed Working Groups on Economics and on Telemonitoring; and co-initiator and Board Member of the European Health Technology Institute for Socio-Economic Research.



Ms Sirinthip Petcharapiruch

Principal, Real World Solutions, IQVIA APAC

Sirinthip Petcharapiruch leads and manages the Health Economics and Outcomes Research (HEOR), RWE, HTA, and market access business for IQVIA, APAC with a focus on the Southeast Asia markets. Her areas of expertise lie in developing pricing and market access strategies, aligning data to evidence requirements in the HTA market, and use of RWE to support healthcare decision-making.



Professor Jianwei Xuan

Professor & Director, Sun Yatsen University

Professor Jianwei Xuan has more than 20 years of research, teaching, and global leadership experience at major Universities such as Sun Yatsen University, University of Florida and Fudan University, and several multinational pharmaceutical companies such as Pfizer and GSK. He has published extensively in the areas of health economics, market access, outcomes research, epidemiology, pharmacovigilance, and mobile health. Jianwei is also advisor to multiple Chinese government agencies regarding health economics and market access policies.



Professor Stephen Goodall

Deputy Director, Centre for Health Economics Research and Evaluation

Professor Stephen Goodall is Professor of Health Economics and Deputy Director of the Centre for Health Economics Research and Evaluation (CHERE) at the University of Technology, Sydney. He is an expert in applied research in the fields of economic modelling, the reimbursement of new health technologies and discrete choice experiments, and has also worked within the pharmaceutical industry. Stephen oversees research projects conducted on behalf of the government and non-government agencies, including health technology assessments for the Medical Services Advisory Committee (MSAC); and appraisal of pharmaceutical and vaccine industry submissions to the Pharmaceutical Benefits Advisory Committee (PBAC).



Professor Ataru Igarashi

Associate Professor, Unit of Public Health and Preventive Medicine, School of Medicine, Yokohama City University

Professor Ataru Igarashi is an Associate Professor at the Unit of Public Health and Preventive Medicine, Yokohama City University of Medicine. Prior to this, he served at the Department of Drug Policy and Management, Graduate School of Pharmaceutical Sciences, The University of Tokyo. His areas of expertise include health economics and pharmacoconomics. Several results from his research, such as vaccination policies, anti-smoking policies and some medications, have been used in the consideration process to inform governmental decisions.



Dr Mingdong Zhang

Chief Medical Officer & Vice President of Strategic Medical Affairs, Boston Scientific Asia Pacific

Dr Mingdong Zhang is Chief Medical Officer and Vice President of Medical Affairs for Boston Scientific Asia Pacific. Mingdong has vast experience in the fields of medical devices, regulation, and academic and clinical research. Having worked at the FDA and National Institutes of Health (NIH) in the United States, Mingdong has provided medical reviews for multiple original premarket approvals (PMA) and 510k submissions on medical devices including in vitro diagnostics, led designs of post-approval studies and performed risk assessment and health hazard evaluations of medical devices.



Dr Yan (Viva) Ma

Outcomes Research Lead HEOR Centre of Excellence, Greater Asia Becton Dickinson

Dr Yan (Viva) Ma is the Outcomes Research Lead of the HEOR Centre of Excellence Greater Asia in Becton Dickinson. Viva has dedicated her career to improving affordability and patient access to innovative treatment strategies across the Asia Pacific region. She has expertise in health economics, reimbursement and outcomes research, and plays an integral role in various research and policy forums, including the International Society for Pharmacoconomics Outcomes Research (ISPOR) and the Health Technology Assessment International (HTAi) Asia Policy Forum.

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