Harnessing the Potential of Digital Health Technologies:

Policy Pathways for Value Assessment and Reimbursement

APACMed Digital Health Committee

Reimbursement Working Group

APACMed

The voice of MedTech

Table of Contents

01 Foreword

Resolving the Paradox

"Digital Health" is not new, and certainly high on the agenda of most government leaders in the Asia-Pacific region as we enter the post-COVID-19 era of our populations. "Digital" more broadly has disrupted the ways in which we interact, connect, transact. While the potential for its applications to health and care are optimistic, if left uncontrolled, Digital Health may become unharnessed or worse, cause detriment. Let us seek to address this tipping point together with proper policy rigor.

Healthcare is an industry of paradoxes in the Asia-Pacific. More than $2 trillion of investment into Universal Health Coverage (UHC) programs ongoing[1], yet less than 5% of GDP allocated[2]. Representing 60% of total global population[2], yet 24% of the medical technology business[3]. "Made In" socioeconomic reforms to mitigate the middle-income trap, yet 70% of medical technologies are imported3. The Asia-Pacific has an opportunity to lean and leapfrog in the medtech field – and necessity is the mother of innovation. But this simply won't happen without a focused policy effort.

Unfortunately, "Digital Health" is likely to fall into the same paradoxes unless we do something differently. For the purposes of this paper, we follow an expanded version of Seth Frank's definition of Digital Health, already adopted more widely by groups such as WHO, summarized as the convergence of healthcare + internet, with various creative tools and applications emerging. Of importance to APACMed and its members is the treatment of Digital Health as a medical use intervention.

But the Digital Health policies of today are typically sitting in a chasm between "no evidence, no adoption" and "no adoption, no evidence". Not surprisingly, much of the scalable Digital Health in the Asia-Pacific thus far lends to unregulated, B2C business models. Such pathways not only undermine prescriptive healthcare reforms like UHC, but moreover create unnecessary frictions between public-private sectors as well as corporate-enterprise forces. Rather than a vibrant, collaborative ecosystem, under-regulated Digital Health fosters more of a "fail fast" mentality than that of evidence-based translational sciences core to a high-quality healthcare system.

The impetus for this position paper stems from APACMed's dedicated Digital Health Committee that was founded in 2020. The Committee emphasizes public-private programming across the Asia-Pacific on critical topics such as cybersecurity, interoperability, and regulatory needs for Digital Health, especially of the medical-use variety. Now the Committee is looking to build appropriate value assessment, funding, and reimbursement frameworks as a means to drive coverage for the adoption and efficacies of Digital Health.

This paper outlines proposed archetypes for Asia-Pacific government leaders as it pertains to Digital Health definitions and context against broader healthcare and socioeconomic reforms, the challenges faced in our under- served populations, and, most critically, a path forward for incorporating evidence-based value assessment and reimbursement best practices. Two coverage archetypes are provided – for mature markets which are predominantly public-funded and seeking to optimize existing UHC systems, and for developing markets with a mix of public-private funding using UHC as lever to achieve "4.0".

We look forward to discussing the concepts together for enhancing the legitimacy of Digital Health as a formal tool for our populations in the Asia-Pacific, especially as we usher in the post-COVID-19 era. The potential is certainly in line of sight; however, harnessing it will require a more hands-on, structured approach.

Sincerely,

Harjit Gill

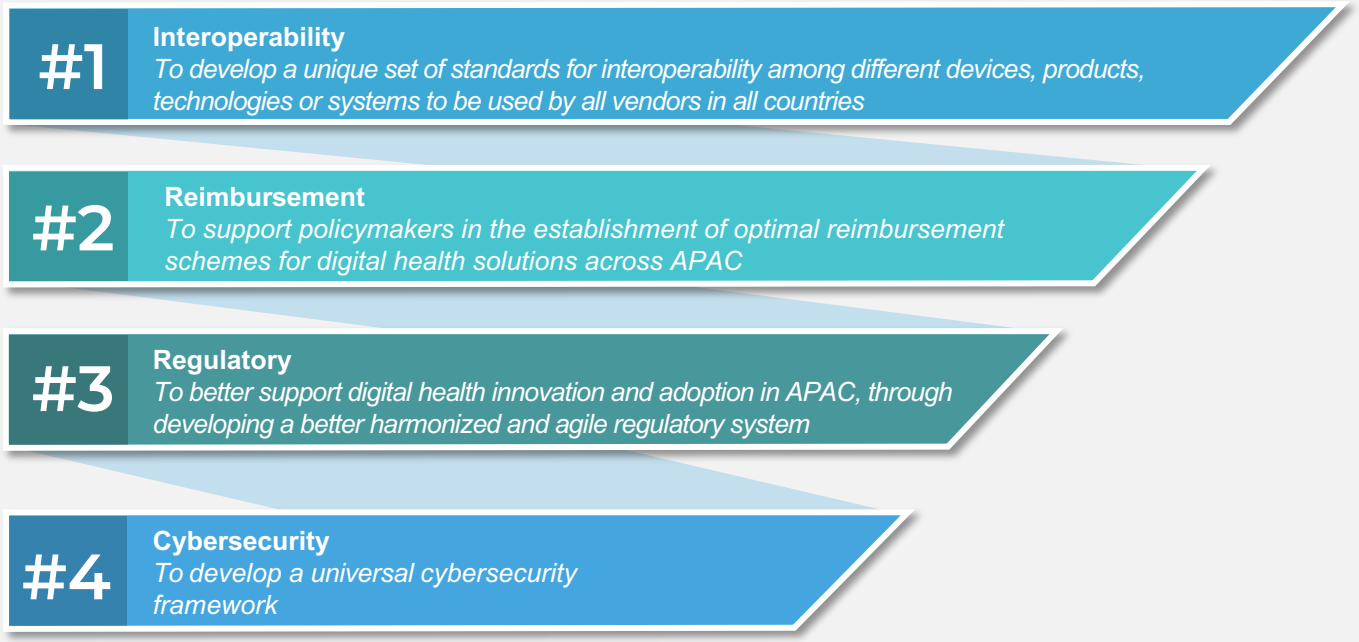
Chief Executive Officer, APACMed

02 Paper Context and Summarized Call-to-Action

One could argue that the opportunity for digital applications into the healthcare industry is at an all-time high. Populations have already become "disrupted" by digital ways of life in terms of speed of communications, how we connect and work, and areas like fintech for payment processing. Many of the legacy inefficiencies in healthcare (lack of access, geographic coverage, information, prevention, patient monitoring) stand to be overcome through digital means. Especially as we enter a post-COVID-19 era, it's time to once-and-for-all take Digital Health seriously.

However, this needs to be done right, as if left unattended or driven purely by under-regulated pathway models, Digital Health will not only fail to deliver on the promise, it may cause detriment as a source of unofficial intervention. This is not the way healthcare, medical technology, and translational sciences operate. Equally, just treating Digital Health like a standard medical device is also not fit-for-purpose. And while the tailored regulatory landscape is improving, this paper calls for greater attention to appropriate value assessment and legitimized funding and reimbursement frameworks that are desperately needed for sustainable adoption of Digital Health.

Fig. 1 - APACMed Digital Health Committee



The Asia-Pacific Medical Technology Association (APACMed) established a Digital Health Committee in 2020 for such a purpose (fig. 1). While the focus of this paper is more aligned to the evidence-based coverage aspects of Digital Health, the APACMed Committee covers a wide range of Digital Health topics with bespoke sets of tools and collateral for government leaders in the Asia-Pacific. For the Digital Health reimbursement archetypes, founding, and policy recommendations, this paper leverages prior APACMed members' own experiences as well as exhaustive secondary research into existing policies in the Asia-Pacific (and globally), surveys, and a database of best practice use cases. In addition, we conducted bespoke stakeholder discussions across the region among payers (public and private), healthcare practitioners, and other key ecosystem players.

The main objectives of the output being, with specific focus on the Asia-Pacific region:

- To explain why current coverage frameworks are not adaptable to Digital Health, in terms of the speed, scale, and sustainability required for Digital Health to achieve its optimum impact;
- To consolidate Digital Health best practices and guiding principles into relatable country archetypes for application across patient pathways, including coverage requirements;
- To provide a set of Digital Health funding and reimbursement policy recommendations, in checklist format, that are fit-for- purpose and foster an environment of continued public- private dialogue.

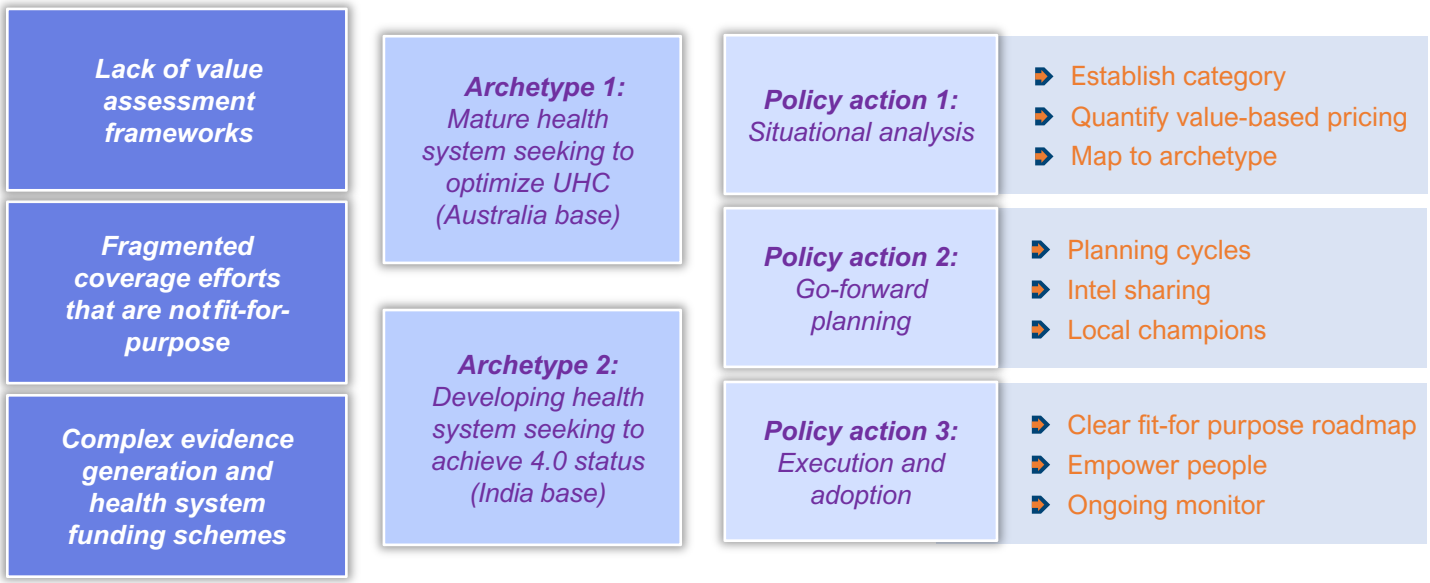
The core issues identified as part of the current landscape are explained in further detail starting on page 14. Fundamentally, these issues boil down to policies that either inappropriately treat Digital Health as an unmonitored B2C type platform, or the opposite in terms of as a pure medical device. The issues can be summarized as follows:

- There is a lack of value assessment frameworks for Digital Health
- Funding and reimbursement efforts to date are fragmented and not fit-for-purpose
- The stringent evidence generation requirements and health system financing schemes is diluting the potential of Digital Health (across public and private sectors) before it starts.

The implications of the above are considerable. With more than 300,000 Digital Health technologies already available in the US, for example, the FDA is working hard on appropriate guidelines including with their recent launch of the Digital Health Center of Excellence[4].

Governments in the Asia- Pacific, along with leading multilateral voices like WHO, are quickly producing blueprint strategies for dealing with the Digital Health boom. As much of the region seeks to provide broader patient access to better healthcare over the coming 10 years, Digital Health offers a potentially cost-effective mechanism to close the gap on equity. But well-intentioned timelines and a focus on a holistic value and benefit to the continuum of care for the most relevant stakeholder for that technology remain lacking, generally let alone specific to Digital Health. The sustainability of our healthcare systems is at stake in the face of unprecedented demographic pressures.

Fig. 2 - Harnessing the Potential of Digital Health Technologies: Policy Intervention



Source: APACMed

The good news, however, is that there is a window of opportunity for policymakers in the Asia-Pacific to take action. It is not only incumbent on governments to drive appropriate rigor around Digital Health value assessment and reimbursement, but moreover strong multi-stakeholder collaboration. Collectively, we can improve the efficacy of Digital Health for the care quality that our populations deserve, and simultaneously accelerate the time-to-market for innovations that will have wider socioeconomic benefits. Herein we propose the below policy considerations for governments in the Asia-Pacific built around two archetypes, that can harness Digital Health through a suitable coverage framework (fig. 2).

03 Digital Health Defined

The term "Digital Health" won't be new to any readers, especially as we enter the post-COVID-19 era when such platforms have finally begun to entice adoption at scale. It is estimated that telehealth, as an example (remote patient diagnosis, treatment, monitoring), increased from 11% penetration to 46% globally over the recent months[5]. In the Asia-Pacific, some of the mainstream platforms have seen usage jump by 150%[6]. The Artificial Intelligence (AI) opportunities in healthcare represent a sub-sector growing at 40% CAGR[7], and, by 2019, already more than 600,000 medical implants have been produced by 3D printing technologies[8].

As leaders, patients, family support networks, surely, we have all had direct experience with the power of Digital Health by now, the good and the watchouts.

We aim for this paper to be focused, however, and therefore leverage a definition of Digital Health from the Seth Frank version written nearly 20 years ago, used as well by many key organizations such as the World Health Organization (WHO). The APACMed Digital Health Committee has embedded the same definition into our programming from the get-go, keeping proposed policy frameworks consistent across Initiatives:

"In Singapore, we use telehealth as our baseline – provision of a medical service over physically separate environments through ICT," said Scott Wong, medical officer in Singapore and Biodesign fellow. "In the physical world, there are already well-defined regulations and reimbursement codes to leverage for Digital Health. Hence the challenge is valuing those technologies that cross the physical divide and into the virtual world, through hardware, software, and the combinations therein." Most of the country stakeholders we spoke to, while there remains some variability in terminology, are increasingly aligning on a consistent description of Digital Health akin to the one above and tied to the WHO's strong efforts.

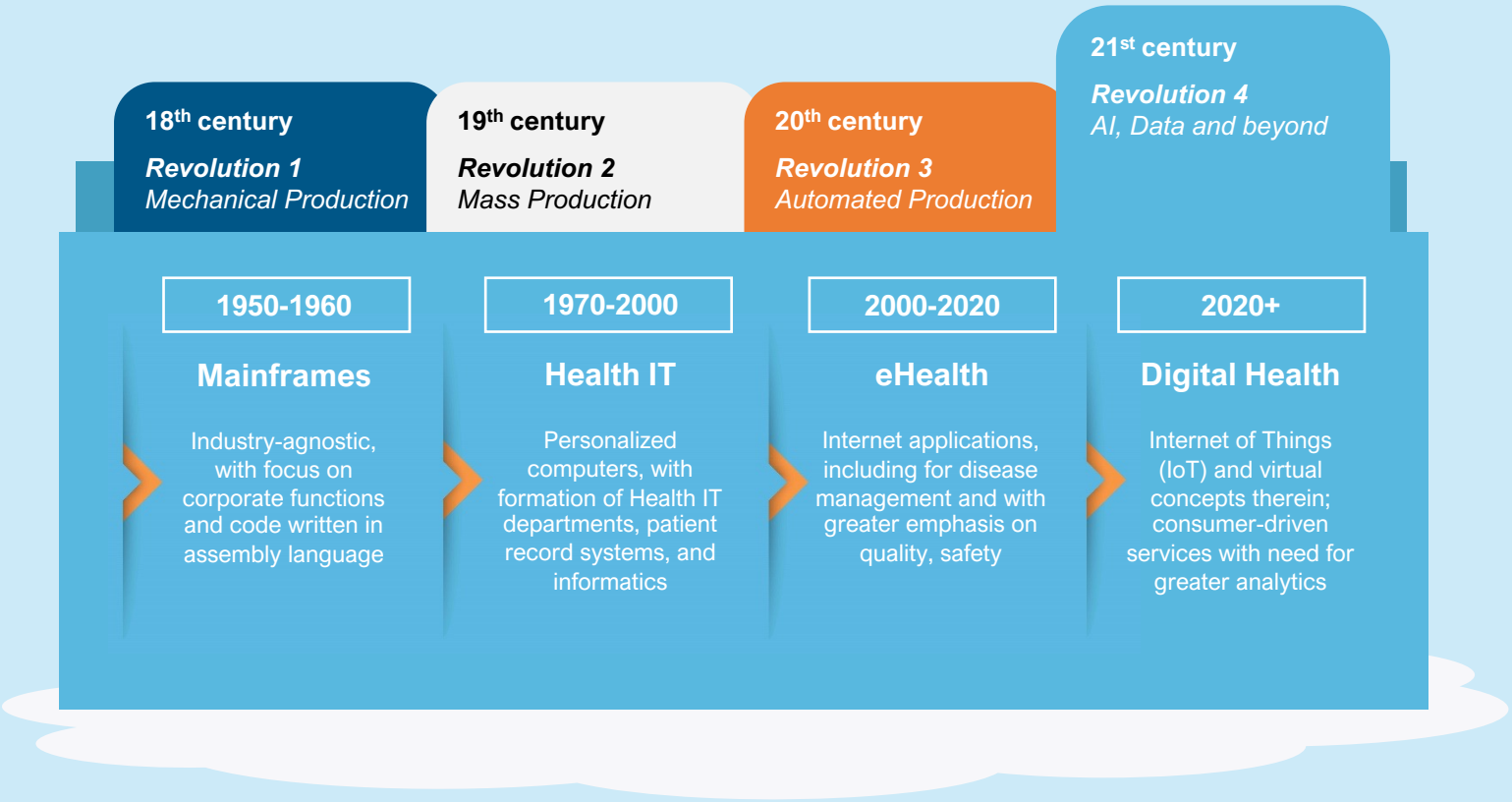
Put simply, Digital Health may be thought of as the application of the internet, and other such digital communication mediums, for healthcare purposes, with a variety of creative tools and applications emerging. At APACMed, we are focused on the treatment of Digital Health as medical use, with bespoke needs that are beyond B2C models yet also not the same as a traditional medical device. Digital Health, and healthcare more broadly, is following tightly along the industrial revolution process, with high expectations for impact therein.

Digital Health Defined:

APACMed's Consistent Messaging in the Region

First introduced in 2000 by Seth Frank, Digital Health two decades ago largely encompassed internet-focused applications and media to improve medical content, commerce, and connectivity. The term Digital Health has now expanded to encompass a much broader set of scientific concepts and technologies, including genomics, big data, artificial intelligence, 3D printing, Software as a Medical Device (SaMD), virtual and augmented reality, robotic surgery, analytics, wearables, biosensors, digital therapeutics (i.e. smart pills), mobile health, companion diagnostics, mobile applications, and telemedicine.

Fig. 3 - The Four Industrial Revolutions: Overlaying Health Technology Progression



Indeed, in a survey of APACMed member organizations, 76% see the emergence of big data and cloud computing as the most relevant Digital Health innovations, followed closely by tools that enable more effective clinical decisions. Equally, members see the lack of Digital Health guidelines, including around data rights, as the most concerning hindrance to progress[6].

Governments around the world are starting to take notice. With already more than 300,000 Digital Health applications available, the US FDA provides formal groupings for Digital Health depending on whether the technology aim is mostly for efficiencies, patient behavior changes and monitoring, or prediction models that guide treatment decisions[4].

Similarly, the European Commission has published its expert panel framework for the digital transformation of healthcare services. Academic centers in the UK, under the Institute of Global Health Innovation, are closely eyeing the new approaches for Digital Health-enabled evidence gathering (e.g., simulated clinical trials and digital twinning).

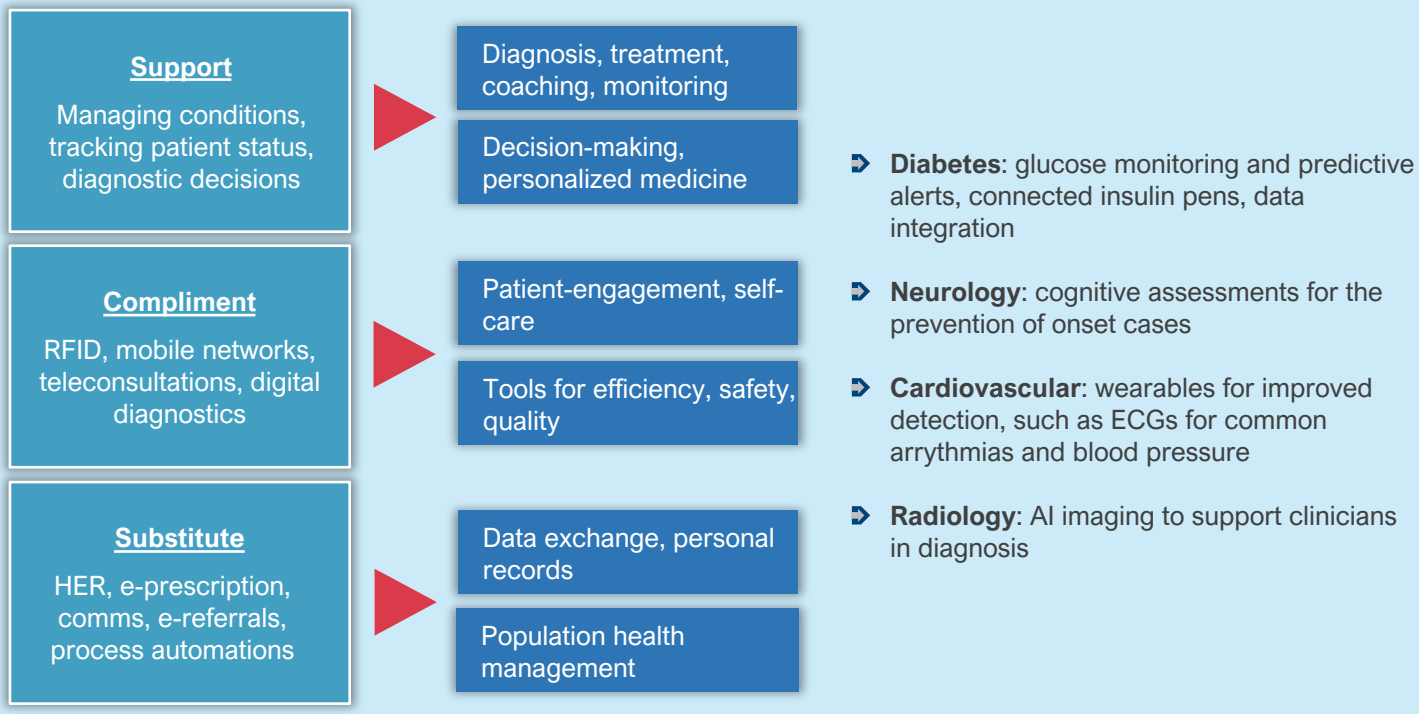
The aforementioned APACMed definition for Digital Health is moreover consistent with the bespoke Health Technology Assessment (HTA) approach now adopted in the likes of Germany, France, and Korea. The majority of stakeholders we spoke to are particularly focused on applications of AI algorithms to healthcare, for decision-making support and with connected medical devices therein.

In Asia-Pacific, countries such as Australia and India, two distinct archetypes to be covered later in this paper, are seeing the potential of Digital Health as scalable solutions to improving healthcare delivery and outcomes through cost-effective means, ranging from healthcare promotion and prevention to therapies and self-management. This has led to the development of National Digital Health Strategy missions locally, to support rigor around the implementation and quality of Digital Health adoption. The situation is ripe in Asia-Pacific – more than 50% of populations reside in hard-to-reach locations, yet with high mobile network (90%) and internet (55%) penetration rates[12]. Especially as we enter the post-COVID-19 era, countries such as China and South Korea are now legitimizing next-gen population care techniques like telehealth.

But, quite frankly, the above won't be enough to enjoy the full promise of Digital Health and, could possibly cause detriment through the ill-use of Digital Health interventions. The current challenge is less about the myriad of tools and applications of "digital" into healthcare, rather more about the appropriate valuation and health system financing models that must stay aligned to evidence-based assessment and decision-making principles. It is for this reason, in our opinion, that Digital Health has yet to truly scale to the hyped potential. Regulatory guidelines, interoperability standards, cybersecurity, and compatible coverage frameworks are all lacking, with this paper focusing on the latter point. More holistic thinking will need to value Digital Health for the clinical, economic, social, and transformative impact on healthcare delivery, across organizational, operational, and personalized levels. COVID-19 pressures have expedited some of the stagnated discussions around Digital Health reimbursement, and we hope our call-to-action will codify it.

"There can at times be a false narrative around Digital Health, that preventative interventions can be the cure-all," said Sangeeta Tikyani, who has led the adoption of HIMSS under India's Ayushman Bharat program and now oversees the "Healthcare at Home" initiative. "We must look beyond the collection of data, and deeper into how the information is used as a trigger point for the new models of care."

Fig. 4 - APACMed Digital Health Committee



Source: EXPH, European Commission. 2019 & APACMed and L.E.K. Consulting, 2020

For the remainder of this paper, we will keep things streamlined. Following the consistent definition of Digital Health provided above, there are a few parameters when considering what is in, and out, of scope for funding and reimbursement policy.

We therefore select a single case study to reference over the course of the document: HeartFlow Analysis, manufactured in the United States, and commercially available in the Asia-Pacific. The HeartFlow Analysis technology has a base in AI imaging for the cardiology pathway, making it a Digital Health software as well as companion to medical use devices. The Digital Health applications are exploding for the cardiovascular space, considered to be the #1 burden of disease category in Asia-Pacific[6]. In addition to AI imaging, we observe other emerging use cases, like remote monitoring of cardiac arrhythmia patients, that will be worthy of valuation and reimbursement by Asia-Pacific policymakers. Such technologies are furthermore relevant to various payer types, and, importantly, HeartFlow Analysis is one of the few examples of reimbursed Digital Health to- date in the region. We will also explain why the HeartFlow Analysis case exemplifies the continued issues with the Digital Health valuation and reimbursement process in the region. Let us explore more together.

These parameters include:

- Focusing on Digital Health solutions that are for clinical and healthcare related use;
- Solutions that are complementary or standalone to core medical devices; and
- Ensuring relevance across a range of payer types (public, private, mixed).

04 Setting the Scene: Health and Care in the Asia-Pacific

The Asia-Pacific is a region of paradoxes when it comes to its healthcare system (fig. 5). On one hand, we are witnessing one of the greatest ambitions in population history through the implementation of Universal Health Coverage (UHC) programs, aligned to the United Nations' Sustainable Development Goals (SDGs) due by 2030, and similar such initiatives aimed at improving the equality and access to care. The interconnected downstream social and financial productivity awards of equality and access efforts are bringing unprecedented levels of focus and investment to healthcare in the region. Yet on the other hand, the majority of countries in the Asia-Pacific are still allocating less than 5% of their GDP toward healthcare, which is half of the OECD-recommended average[2]. Even those more mature markets in the region are struggling to simultaneously balance maintain sufficient financing against rising population health demands, particularly during a tightening of fiscal resources following the COVID-19 pandemic.

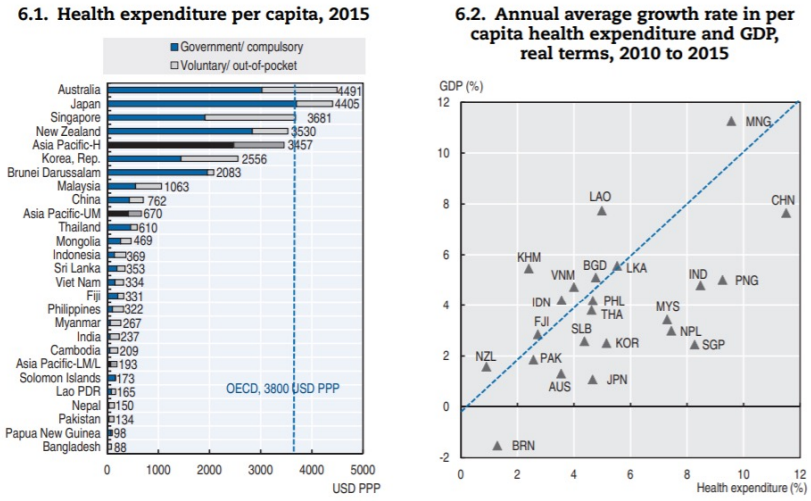
Fig. 5 – Sustainable Financing and Universal Health Coverage in Japan, Singapore and Indonesia

	Sustainable Financing		*Universal Health Coverage*	
JAPAN 	Current health expenditure as a % of GDP **10.9%**	Out-of-pocket expenditure % of current health expenditure **13%**	Life expectancy **84 years**	UHC Service Coverage Index (SHI) **83**
INDONESIA 	Current health expenditure as a % of GDP **3.1%**	Out-of-pocket expenditure % of current health expenditure **37%**	Life expectancy **71 years**	UHC Service Coverage Index (SHI) **57**
SINGAPORE 	Current health expenditure as a % of GDP **4.5%**	Out-of-pocket expenditure % of current health expenditure **31%**	Life expectancy **83 years**	UHC Service Coverage Index (SHI) **86**

Source : KPMG [13]

Health system design, financing, and delivery in the Asia-Pacific are not all created the same either. A variety of models in terms of public-private mix, single payer versus other social or individualized insurance schemes, and centralized versus devolved decision-making are observed. Each model in its own right is designed with local philosophies and intentions in mind, meaning that any such related policy direction, including for Digital Health applications, will need to be considered on a localized basis as well. According to Tikyani in India, for example, the current baseline is teaching doctors how to use a computer mouse, much less high-end technology solutions. Such dynamics are especially true in light of the ongoing investment into healthcare transformations. Dr. Alvin Marcelo, IT SVP and CMIO of St. Luke's Medical Center in the Philippines, agrees that reimbursement strategy, including for Digital Health, must abide to the overarching vision for legislation of healthcare equality and access.

Fig. 6 - Health Expenditures per Capita and Growth Rates



Source: World Health Organization[14]

Our populations are getting older and more expensive to care for. Such viewpoints are already quite well-published, including the ramifications from the emergence of lifestyle-related medical conditions while also bearing in mind the lingering, punishing effects of infectious diseases (as the current circumstances have reminded us). Indeed, the conversation has now evolved into one of sustainability for healthcare systems, even looking beyond SDGs 2030.

Several countries in the Asia- Pacific remain in their "demographic dividend" period, an open investment window that is slowly closing in order to ensure exit from the "middle income trap" and that future generations are well-protected, with clear socioeconomic goals to achieve a "4.0" status of industrial development. Healthy and productive peoples improved medical screening and diagnosis, and future- proofed financing mechanisms through composite insurance schemes are key, especially when seeking to reduce out-of-pocket healthcare expenditures that are a leading driver of poverty.

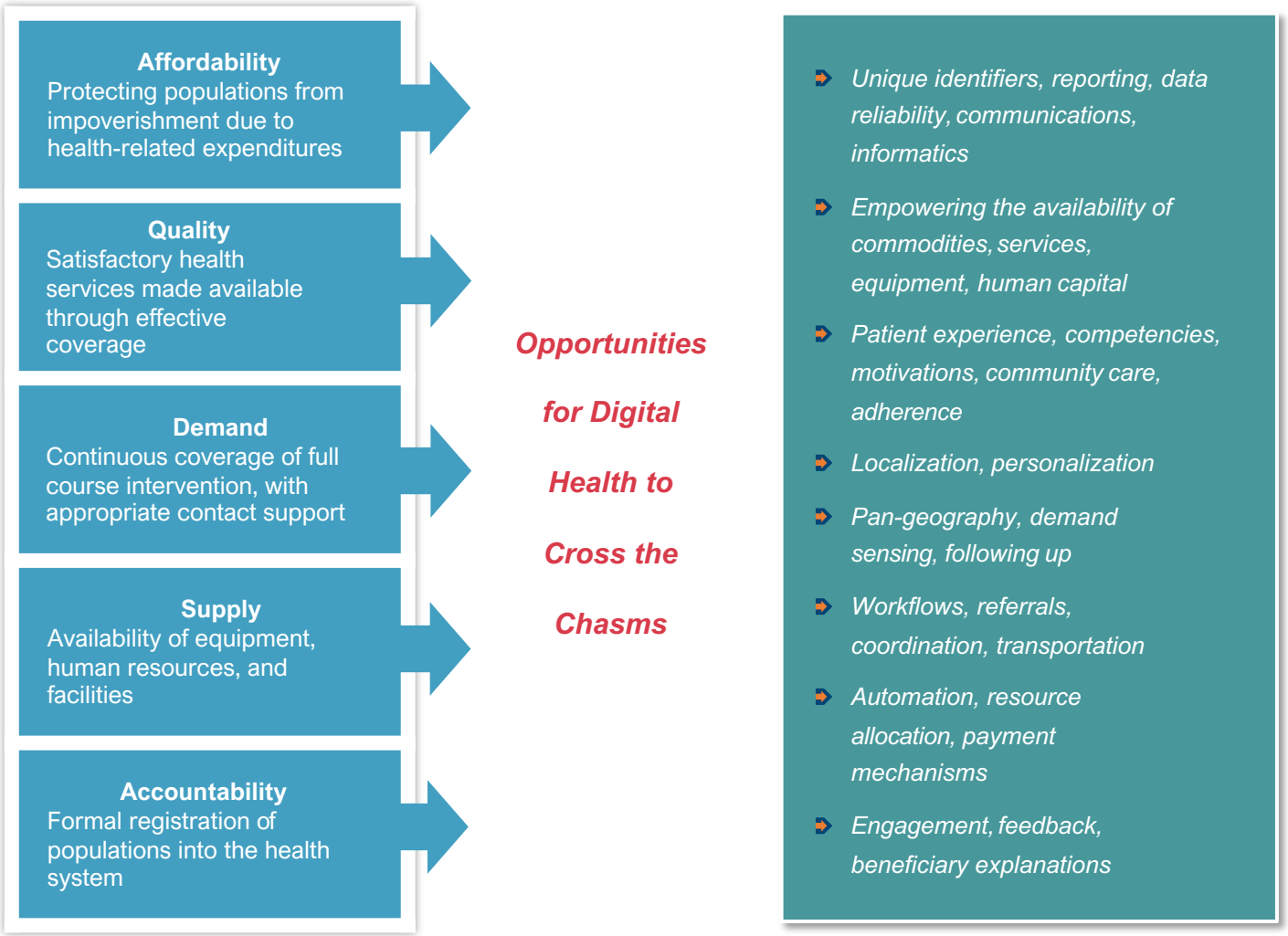
Also, key is looking at the next generation of healthcare delivery models, including through digital means and backed by evidence-based decision making. If Asia-Pacific policymakers were to champion an initiative aimed directly at resolving the healthcare equality and access issues, transformation of the Digital Health founding and reimbursement ecosystem, and the associated underlying infrastructure requirements, would be one of great value for money.

"Digital Health coverage by social and commercial insurance programs can help people to obtain healthcare in a more accessible, affordable, and scalable way," said the WeDoctor team in China, with 27 million monthly active users and more than 250,000 doctors onboard. WeDoctor have supported the direct impact on socioeconomic status too – in Henan province through the adoption of Digital Health, poverty associated with healthcare expenditures has decreased to 20% as compared to the 44% country-wide benchmark[6].

At APACMed, we seek to drive reconciliation of the ambition for healthcare transformation against the a forementioned challenges ahead through the use of medical technology innovation

In our seminal study about the footprint of medical technology in Asia-Pacific, we outline the potential for improving life expectancies, hospital length- of-stay, surgical rates, among wider economic benefits of the industry in the form of job creation and a bolstered research community. Subsequently, we established the APACMed Digital Health Committee given the similarities in focus and the clinical, economic, social, transformative impact across the interventions, when managed in a medical-use way. In reviewing the categories of barriers facing Asia-Pacific policymakers in realizing their ambitions, the overlay of Digital Health technologies gives clarity as to the connection between healthcare system design and adoption of novel techniques (fig. 7):

Fig. 7 - Plugging the Gaps: Health Equality Ambitions + Digital Health Solutions



Source: World Health Organization, 2019[15]

We assume most Asia-Pacific policymakers are aware of their demography pressures as well as the emergence of Digital Health as an appealing intervention to embrace. So, other than the extreme circumstances of the COVID-19 pandemic, what is truly going to cause a turning point in the adoption of Digital Health in the Asia-Pacific? Enter the engaged Digital Patient. Born out of systems designed around quality and safety practices for disease management, citizens are raising their voices about the need for greater personalization in their health and care journeys. As aforementioned, populations in the Asia-Pacific, with few exceptions, are well-connected to the internet, enabling information to flow freely across borders, pathways, experts, and other healthcare ecosystem stakeholders.

Such "consumerization" of healthcare is long discussed in the context of more "patient-centric" models, which Digital Health is now unlocking. The Digital Patient strives to be informed and more involved in their healthcare decision- making, aligned to their personal socioeconomic needs. The demand for personalization could be exactly what Asia- Pacific policymakers require in order to usher in their "4.0" statuses, but only with appropriate policy and rigor around evidence-based assessments and access decisions. It's easy to see Digital Health and the Digital Patient as a quick, cost-effective answer; it's another, more sustainable strategy to redesign healthcare systems so as to appropriately integrate and provide coverage for these interventions.

Fig. 8 - HeartFlow Analysis: How the Story Began

US-based medtech company founded in 2017 out of Stanford University; valued at $1.5 billion in Series E fundraise

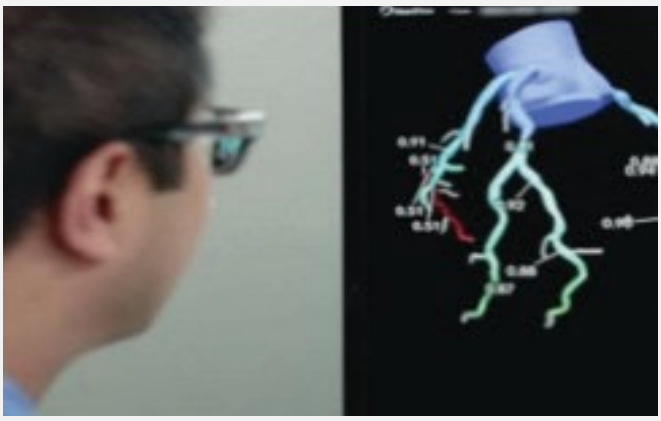
Using advanced algorithms to build a personalized, digital model of coronary arteries from a CT scan image, and to apply computational fluid dynamics to project blood flow and FFR (color-coded heart modelling to identify blockages)

86% accuracy against gold standard, with majority of analysis completed in <5 hours; also reduces the need for invasive coronary angiograms

Up to $4K in cost avoidance per process

CE-marked and FDA approved, applied in more than 30,000 patients globally across 200 institutions

- *61% of patients avoided invasive angiogram*
- *26% cost reduction compared to current standard of care*
- *Zero adverse clinical events among patients who had angiograms canceled*
- *Improved quality of life*



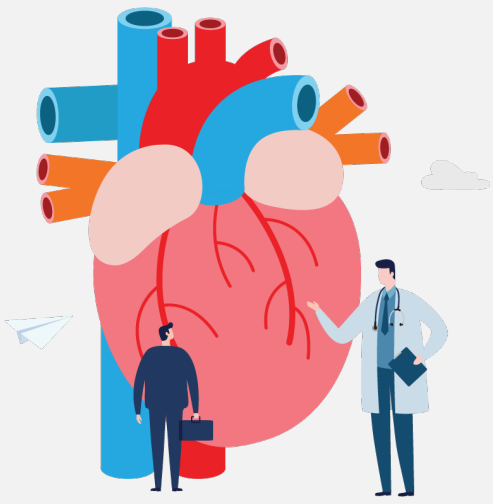
Source: APACMed and L.E.K. Consulting, 2020[11]

The journey for the HeartFlow Analysis team was far from straightforward, however (fig. 8). A two-year approval process, at a cost and lifecycle much beyond the ambitions of Digital Health innovators, and with a level of clinical evidence required that does not adequately value the downstream benefits that Digital Health can offer to our care pathways, goes to show that we still have work to do in designing a coverage system that is fit-for-purpose rather than relying on the traditional mechanisms.

As we have often advocated for in the past, an "investment" into healthcare systems and novel medical technologies does not have to be viewed as a cost alone either. Investment into population health is investment into population wealth, when done correctly. In line with the definition of Digital Health provided in this paper as well as the intended call-to- action for reimbursement policy, we fundamentally believe in the promise of a healthy Digital Patient and ecosystem to drive Asia-Pacific policymaker socioeconomic ambitions.

Appropriate and timely evidence-based assessment and funding and reimbursement frameworks for Digital Health are the answer. "Value, underpinned by quality and accessibility, at a good cost, continue to be the core axioms of our health system strategy," said Wong in Singapore, who is a former regulator over Digital Health and was involved in designing the "sandbox" concept for piloting novel technology interventions.

"Quality is perhaps the most difficult to measure, but also the ultimate determinant of reimbursement. Understanding patient journeys, comparing current to future pathways and the risks therein, create alignment to the reimbursement codes. This is true whether it be a product- or service-orientated delivery model."



05 The Challenges Ahead – Hype or Hope for Digital Health?

Underserved populations in the Asia-Pacific, amongst developed and developing countries alike, are now in crisis mode. While in some respects such a "stress test" of health systems in the region is causing a spur of innovation and much-needed enhancements, we would expect countries to be operating under constrained resource circumstances for the foreseeable future. It's time to change course, and Digital Health could well be a key cost-effective tool in the box for Asia-Pacific policymakers. But using Digital Health to address the disparities and inequalities in healthcare systems requires an appropriate enabling environment, including sufficient resources and infrastructures.

The promise of Digital Health could fall into the same over-hyped traps that other disrupters have faced over time – much like the fates of smart appliances and virtual reality which, despite great intentions, have yet to achieve universal scalability. What's more, there are a number of public cases of Digital Health causing harm due to ill-use or otherwise under-regulated approaches. Telehealth platforms as a first encounter mechanism for high-risk, comorbid patient diagnosis require a closer look at the embedded algorithms. Digital tools that are providing advice for nutritional and medication adherence purposes could be deemed equivalent to seeking help from an unlicensed physician. Even the digital platforms themselves, on which modern adults spend approximately 12 hours of their day, can lead to addiction and mental ill-health[16].

We summarize here the three major Digital Health challenges for Asia-Pacific policymakers to be aware of in the context of this paper:

- Lack of appropriate value assessment techniques
- Fragmentation of coverage efforts, and
- Variability in evidence generation that mirrors the complexities of financing models in the region.

While we also suggest to policymakers that the lack of regulatory formality around Digital Health itself and guidelines therein are a cause for concern, these topics are the focus of other papers from APACMed.

Challenge #1:

Lack of Appropriate Value Assessment Framework

We don't belabor the point about value assessments in this paper, as there is sister documentation by APACMed specifically focused on the topic for Digital Health. But it's important for policymakers in the region to understand that such a value assessment mindset is a critical predecessor to strong and timely reimbursement frameworks. As they say, what gets measured gets paid. And that has a number of ripple effects to wider health and socioeconomic ambitions that we will explain.

Considerations for policymakers regarding Digital Health value assessment may include:

- Do you have a consistent set of definitions and categorizations for Digital Health, especially those technologies which intersect with clinical workflow and patient journeys?
- Are the value assessments being used tailored to Digital Health, or just a replica of traditional medical devices or other similar existing models?
- Does the value assessment include clinical as well as economic and social impacts to healthcare delivery, at population wide as well as organizational, operational, and personalized levels?
- Does the valuation process consider the shorter lifecycle management of Digital Health solutions?

In our experience in the Asia-Pacific, the common answer is "no" which stands to severely undervalue Digital Health and therefore, undermine overall healthcare transformation efforts.

Let's take HTAs as a tool for national reimbursement decisions of drugs and medical devices. Policymakers in the Asia-Pacific have done an admirable job of embracing HTAs as a mechanism for taking a more holistic look at how medical innovation can benefit its population, and therefore be rewarded accordingly. Such a mechanism encourages international collaboration, innovation, and improvement in access to the latest health and care interventions available.

For Digital Health, on the other hand, there is no specific value assessment in the region and thus the use of general HTAs for medical device purposes are often deployed, especially for those Digital Health technologies that are embedded within the medical devices (link here to APACMed's global assessment of HTAs for the purpose of Digital Health). Valuations are then off- kilter, and new Digital Health technologies are restrained. Without proper reward nor benefit realized. Robotic surgery for example, already used in over 500,000 cases globally annually and expected to represent 35% of surgeries over the coming few years, is perceived as a more expensive, complex alternative solution and therefore it remains unclear as to the coverage intentions by governments[17]. Even in Korea, which has made attempts at HTA guidelines for Digital Health tooling such as AI medical imaging and 3D printing (fig. 9), places much greater emphasis on therapeutic effect of Digital Health and other downstream values which tend to be overlooked. Thus we encourage Asia-Pacific policymakers to keep working out an appropriate mechanism to value, and ultimately fund, Digital Health. The ramifications go beyond policy too because, subsequently, clinicians, caregivers, and patients are unclear how to get in line with Digital Health credibility and compliance requirements. The result is an undue stressor of the ecosystem needed for digital innovations to thrive and be able demonstrate effective use and commercialization, especially relative to competing innovator opportunities in other fast-moving industries.

Fig. 9 - HeartFlow Analysis: How the Story Began

AUSTRALIA
Australia's National Digital Health Strategy is intended to be a general strategy document and does not include any value assessment guidelines. Although telemedicine is reimbursed in Australia, there are no dedicated value assessment frameworks at the moment.

CHINA
The document "Technical Guideline for Telemedicine Information System Construction" issued by the National Health and Family Planning Commission (NHFPC) in 2014, covers only the blueprint for the creation of an interoperable and uniform telemedicine service network. Even before the pandemic, the Chinese government has supported the use of DHTs extensively and the lack of a comprehensive reimbursement model for DHTs is its biggest drawback. Hence, with the acceleration of DHTs in China, a value assessment framework for DHTs would be developed sooner than expected.

VIETNAM
Vietnam does not have any reimbursed DHTs due to the lack of value assessment frameworks.

JAPAN
Currently, DHTs do not have a specific assessment framework and if at all evaluated alongside medical devices

SOUTH KOREA
South Korea is only country in APAC that has developed a value assessment guideline for DHTs, namely AI and 3D printing technology

THAILAND
The Health Intervention and Technology Assessment Program (HITAP) has developed comprehensive clinical and economic evaluation guidelines, however these need to be modified for DHTs.

INDIA
In the midst of the pandemic, in March 2020, the Medical Council of India released the telemedicine practice guidelines. However, there was no information regarding the reimbursement of telemedicine services.
The HTA agency in India – HTAIn, which was established only in 2018, would need several years to develop an assessment framework for DHTs.

Source: APACMed, 2020[6]

Challenge #2:

Fragmentation of Coverage Efforts

Extending on the above, coverage remains one of the single largest barriers to the successful adoption of Digital Health in the Asia-Pacific, technologies which have otherwise witnessed a tremendous upsurge during the COVID-19 pandemic. For example, the Australian government lifted reimbursement restrictions on telehealth services, allowing its Medicare program to subsidize at both the primary and specialty care levels. In Japan likewise, the Ministry of Health, Labor and Welfare (MHLW) now funds online medical consultations and home delivery of prescription drugs. While such next-gen coverage strategies are welcomed, we would urge for a sustainable system to scale up the positive direction.

"We still have some way to go, given that the large majority of teleconsultations are being conducted over the telephone," said Bettina McMahon, Australasia Institute of Digital Health Chair. "We're making huge gains during the COVID-19 situation, but there remain trust issues about the quality, safety, and patient experiences in using Digital Health. The main focus for us now is to make a stepwise approach forward, not to remain stuck or even fall backward."

It is clear that Digital Health funding and reimbursement is a topic of discussion for Asia-Pacific policymakers; however, the frameworks, where they do exist, are inconsistent at best. Some in, some out across telemedicine, remote monitoring, AI, 3D printing, SaMD, robotic surgery.

HeartFlow Analysis, our main use case for this paper, is one of the few successful examples in the region after having achieved both approval and reimbursement in Japan despite challenges with lengthy timelines and high evidence requirements. Other well-known technologies such as InferRead (medical imaging in China), Selena+ (diabetic retinopathy deep learning in Singapore), and VunoMed Bone Age (pediatric bone analysis in Korea) remain in the purgatory of approved yet unreimbursed. The medical technology industry as a whole has made significant advances in international harmonization through organizations like IMDRF and APACMed, but the same rigor has not yet landed for Digital Health.

Fig. 10 – Approaches to Reimburse Digital Health Technologies

Health System Layer	Driving Entity	Reimbursement Approach
Multilateral	• HIMSS • FDA • WHO • European Commission • IMDRF • UK NHS	• Interoperability criteria for monitoring personal health, wellness • Various including benefits framework, mobile apps, algorithms • Product lifecycle evaluation and validation general framework • Standalone software qualification and classification • SaMD definition, risk categorization framework, clinical evaluation • NICE evidence standards framework and code of conduct
Geography	• Australia • China • Japan • Korea	• Telehealth, remote monitoring, CGM services increasingly covered • Guizhou Province pilot program for telemedicine reimbursement • Some reimbursement of remote monitoring, exams, CGM • Partial reimbursement CGM, likely leading to full coverage
Intervention	• HeartFlow Ana • da Vinci Robo • FreeStyle Libre • Space Pump • VNS Therapy	• Reimbursed in Japan (AI imaging for cardiology) • Reimbursed in Japan, Korea (robotic surgery) • Reimbursed in Japan, Korea, Australia (glucose monitoring) • Reimbursed in Korea, Thailand, China (smart treatment) • Reimbursed in Japan, Australia, Taiwan, Korea (neuromodulation)

Source: APACMed, 2020[6], C. Guo et al, Nature, 2020[4], and APACMed and L.E.K. Consulting, 2020[11]

There can at times be confusion around ownership of the problem too. As per the private insurers we spoke to, reimbursement of healthcare services and products is done on more of a procedural basis, in the private sector itself as well as for private patients who present in the public sector. Therefore, the delivery of the procedures, including use of Digital Health interventions, is not overly transparent to the payer. The situation is potentially becoming even more opaque with the shift to bundled reimbursement models. And while some programs are underway to drive cohesion (e.g., Health at Home trials and commitments to telehealth in Australia), the question of true efficacy and cost effectiveness remains. Dr. Marcelo suggested a similar phenomenon in the Philippines as the per case reimbursement rate essentially lumps together the procedural elements.

The result is that Digital Health coverage policy is not fit-for-purpose. It is either too loose (allowing under-regulated adoption to occur, as is the case with the plethora of B2C wearables landing in the markets) or too stringent (defaulting to a traditional medical device mentality.) In Korea for example, despite progressive discussions, all AI-related medical tooling applications to date have still been classified as "existing technologies". Such rhetoric versus reality affects the current slate of Digital Health technologies coming to market, and moreover the pathways for the future of such innovations.

"For now we cover Digital Health using the current reimbursement system, which comes down to a doctor/patient level and they must be convinced of the value"

said Dr. Joo Youn Kim of the National Evidence-Based Healthcare Collaborating Agency in Korea, who recently formed a special sub- committee to pilot Digital Health valuation across health, clinical as well as social dimensions, including use cases along the cardiovascular space; the pilot concluded with an understanding that qualitative assessments, beyond quantitative, for Digital Health are important in order to see the holistic picture. "In the future, we need to think about new reimbursement categories, and to align the appropriate Digital Health valuations with industry," said Dr. Kim.

Challenge #3:

Variability in Evidence Generation That Mirrors the Complexities of Financing Models

Combining the above two challenges together (value assessment + funding and reimbursement policy) produces a side effect of variability in evidence that then makes a government's life very difficult in the realm of Digital Health. Simply put, Digital Health must not be evaluated like a traditional drug or medical device. Rather than age-old techniques like a double-blinded randomized controlled trial, we need more pragmatic, adaptive studies that harness the power of Digital Health's real-world data and simulation capabilities. Unlike for traditional medical devices and drugs, wherein most cases hard clinical end point were a measure of success; for digital health, we could look at efficiency gains, softer and yet meaningful clinical gains that saves and improves lives. New thinking is emerging around concepts such as stepped wedge or interrupted time series studies, for example. This means greater flexibility in the detailed process evaluations running alongside impact evaluations in order to better grasp the impact of Digital Health interventions over time.

And this is where the paradox of Digital Health is born – "no evidence, no adoption" versus "no adoption, no evidence".

We see some countries attempting to boost innovation of Digital Health through specific faster pathway (like Korea), and others seeking to further control Digital Health so as to avoid a spiraling situation against what is otherwise a very targeted health system transformation program (like China). The Digital Patient, in the meantime, is forced to wait in the wings.

Innovators are also caught in the middle. Balancing R&D budgets between product development and clinical studies in light of an unclear and lengthy reimbursement pathway. Operating on anecdotal evidence in an effort to drive agile validation yet cognizant of allocating resources (already scarce) to robust cost/benefit analysis. Current timescales to bring Digital Health solutions to market under fully regulated channels is several years, which is beyond the typical lifecycle of any digital initiative and often scares away the investor communities. The Digital Health reimbursement topic is greenfield for everyone; hence we recognize the need to take time to assess, learn, pivot our collective strategies.

Fig. 11 - HeartFlow Analysis: Reimbursement Learnings Thus Far

Timelines

- *US reimbursement (Medicare) from Jan 2018*
- *UK reimbursement (ITP) from Apr 2018*
- *Japan reimbursement from Dec 2018*

Monetization Model

- *Flat fee per test analysis performed*
- *Mix of public, private payer coverage*

Reimbursement Factors

- *Clinical evidence: matching/improving SoC, with peer-review articles, patents filed*
- *Cost savings: fewer invasive procedures*
- *Advocacy: Evidence Street, NICE, ACC, AHA*
- *Partnerships: coverage model proven through existing commercial payer arrangements*

Japan Findings

- Local preferences: strong medical community support for targeted tests and cases, especially use of CT
- Unmet need: physicians keen to more effectively diagnosis patients without overburdening the tests
- Access: reimbursement seen as a pathway to drive greater adoption of interventional diagnosis

"We were able to see first-hand how HeartFlow Analysis improves patient management and avoids invasive procedures. Reimbursement enables more physicians and patients to obtain these benefits."
– Wakayama Medical University

Source: APACMed and L.E.K. Consulting, 2020[11]

Importantly, while in the HeartFlow Analysis case the company was ultimately able to supply the required clinical evidence, other Digital Health technologies will continue to struggle. Many innovations provide health systems with greater efficiencies and accuracies outside of the traditional workflows, making it harder to comply into current value assessments. The real value, clinical as well as socioeconomic, may be realized further downstream. And this is precisely where the funding struggles tend to materialize. Policymaker attention to the evidence and adoption paradox, and the need to have a wider scope of benefits that Digital Health can bring, is key.

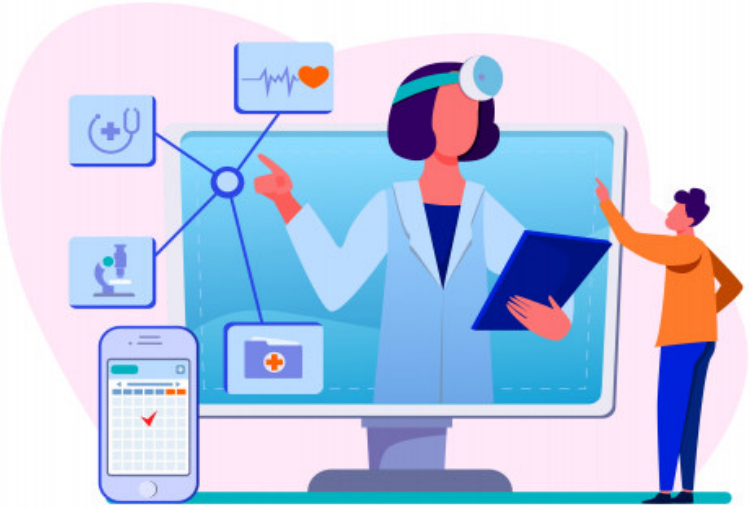
Coverage systems in the Asia-Pacific are already complex – a variety of models, some adopted from the West, others self-designed for local needs, and still others with heavy reliance on out-of-pocket sources such as co-payment. To attempt to overlay the aforementioned complexities of current Digital Health policy strategies against the current complexities of financing models in the region is creating a spaghetti web of impossible delineation. Instead of evolving our health systems in the Asia-Pacific toward the vision of value- or outcomes-based schemes (which we, as APACMed, firmly support), we are instead creating alternative pathways that do not serve the public nor the private sector well. In Japan for example, programs like "Advanced Medicine", home-based care model budgets, and even private insurance coverage for Digital Health are giving a false perception of access to innovation yet in reality only approving, not appropriately valuing and reimbursing, the technology solutions. In China, Waterdrop, a peer-to-peer platform, has emerged as the leading funding channel for medical expenses.

Even pharmaceutical companies are getting into the Digital Health game, pushing forward on companion diagnostics partnerships as a means to expand the reach of their medications. While all helpful, these techniques should not replace a government's role in proper founding and reimbursement for a sustainable ecosystem. "Digital Health advancements have become unnecessarily privatized," said Wong in Singapore. "Private insurance coverage in return for data exchange, valuing the number of users as a form of currency. Governments need to think more holistically about the healthcare models, and wider social needs, that Digital Health can support." Tikyani, likewise, has observed more creative policymaking in India yet with the ultimate burden still often residing with on individual pocket expenditures. "There are a variety of Digital Health solutions being pushed now, each with their own economic analysis in order to seek government approval. It's time to reconcile the priorities and to involve all stakeholders, public and private, so as to ensure the policies are not just sitting in an office."

The promise is overwhelmingly encouraging. The aforementioned WeDoctor in China is able to connect more than 7,200 hospitals across 30 insurance schemes in order to drive a frictionless patient experience[6]. Alison Verhoeven, CEO of the Australia Healthcare and Hospitals Association, while recognizing that the hospital reimbursement framework is indeed tied mostly to the procedural set, is already seeing the substitutional reimbursement happening across the care levels. So the capacity to adopt Digital Health is there, and, in Australia at least and including for the most marginalized communities, consideration for transitional constraints such as retaining periodic live visits are being put in place. For Verhoeven, the same questions remain about the stickiness of such trends as well as how the overarching Digital Health coding is going to play out.

"More must be done from a value assessment and investment reimbursement perspective," said Verhoeven, "and in particular we need to get ahead of the AI applications for healthcare." Professor Ataru Igarashi at the University of Tokyo agrees: "We are still at the stage of using Digital Health as a replacement for existing therapies Rather than as a new treatment. Therefore the friction lies in increasing development costs of advanced interventions battling against conventional therapy valuations that remain unchanged."

While perhaps these issues are not new information for Asia-Pacific policymakers, we hope the messaging is clear. Lack of Digital Health value assessment, fragmentation of coverage, and variability of evidence/financing is undermining Digital Health-driven socioeconomic reform efforts in the region. Digital Health and related care systems deserve better policy rigor. Next, we introduce frameworks for consideration, including with breakdown by Asia-Pacific country archetype – one for the mature UHC models seeking optimization, and one for those aiming to arrive more quickly at the Sustainable Development Goals (SDG) finish line.



06 Digital Health Valuation Archetypes for Funding and Reimbursement

As the aforementioned sections have gone to show, the combination of high unmet need in the Asia-Pacific plus the transformation potential of Digital Health innovation has created a powerful platform for ushering in the next generation of health equity and access. However, until recently, policymakers in the region have tended to rely on existing medical device policies for Digital Health or none at all, allowing under-monitored experimentation to occur. Let us break this paradox of adoption and evidence – the unique lifecycles, offerings, and risks of Digital Health call for revised frameworks that are fit-for-purpose.

The healthcare industry, public and private sector alike, are already quite familiar with evidence-based assessment and decision-making using randomized clinical trials. Yet to-date, few Digital Health technologies in the Asia-Pacific have been studied in such as manner, perhaps rightly-so. Simulation, on the other hand, is a methodological foundation for human behavior experimental research, the concepts of which we can apply now to Digital Health technologies. For the innovators, developing the technology itself is often not the hardest part; finding the right outcomes to demonstrate value and to articulate benefit in a timely manner is the tall order. So let us seek to support the ecosystem through consistent framework guidance. One recent survey estimates that proper simulation and economic-effectiveness analysis actually reduces the cost of Digital Health product development by up to 80%[6], not to mention the positive knock-on effects in terms of greater scalability, flexibility, feasibility, and patient engagement techniques down the line. Such an approach to Digital Health is already being applied in places like Denmark and the UK. What's more, Digital Health-appropriate evidence generation (a la real- world data) actually allows improved post-market value validation, which is certainly a key contemporary strategy being deployed for access to medical technology innovation.

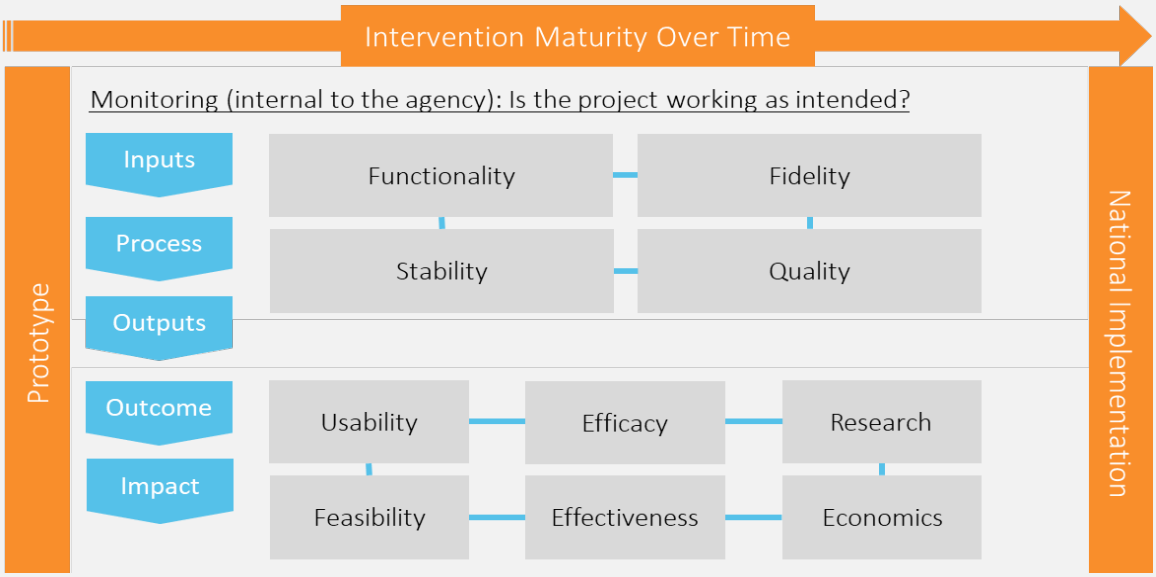
Fig. 12 - Evidence generation academic models for digital health

Published	Tool	Description/Applications of Evidence Generation
2006	QUIPS	• Six factors to consider for evaluating validity and bias • Best for prognosis models (including individualized predictions)
2008	RoB2	• Domains to guide evaluation of trial features and risks • Best for randomized studies (including parallel group trials)
2016	ROBINS-I	• Seven-factor risk assessment of bias in non-randomized studies • Best for non-randomized studies
2019	PROBAST	• 20 questions for applicability of prediction model studies • Best for predictive models (including CDS algorithms)
2019	Digital Health Scorecard	• Technical, clinical, system validation academic framework • Widely relevant to variety of digital health solutions

Source: C. Guo et al, Nature, 2020[4]

The WHO guidelines (recently updated and highlighting the current limitations of existing evaluation processes), then, provide an initial proposal for a holistic socioeconomic valuation of Digital Health. The guidelines cover various domains and criteria such as effectiveness, accessibility, and resource-use. Now the task is the Digital Health-applicable adoption and tracking of such mechanisms, tied back to the real-world data point. There are also gaps between quick, lower-cost approaches applied at the early stages of Digital Health product development versus those required for higher- cost models under a broader stakeholder approval base. Any valuation approach must match the agile development lifecycle more commonplace for Digital Health technologies, including those of the medical-use variety

Fig. 13 - HeartFlow Analysis: Reimbursement Learnings Thus Far



Source: World Health Organization, 2019[1]

Evaluation (external to the agency): Is the project yielding the desired effect?

Similar guidelines such as the European Commission's Joint Action to support the eHealth Network (JAseHN) and Multi- Criteria Decision Analysis (MCDA) are at the disposal of Asia- Pacific policymakers.

We previously touched on HTAs in this paper and won't belabor the point, only to say that HTAs are a potential valuation framework for Asia-Pacific policymakers to consider though, as it stands, few bespoke standards have been designed that are fit-for-purpose for Digital Health technologies (link here once again to APACMed's global analysis of HTAs for Digital Health). It is the view of APACMed that, while HTAs are a model being more widely adopted for medical technologies in general, there are probably better ways to evaluate the actual value of Digital Health technologies. As it stands, HTA frameworks in the Asia-Pacific are already quite variable:

Fig. 14 – HTA requirements for reimbursement across APAC

In most markets, some form of HTA is required by the various evaluation committees

Country	Are there HTA requirements for reimbursement?
Australia	• For new medical technologies that do not have an existing MBS item describing the medical service, MSAC requires a comprehensive HTA review process, which includes the submission of extensive clinical and economic evidence • No option for accelerated review available currently
Korea	• New HTA program for medical technologies was introduced in 2007, which considers the evidence for safety, efficacy, and effectiveness and proposes a recommendation to a 20-member committee • Localized data preferred for evidence generation, while cost data must be local
Japan	• Formal HTA was launched in April 2019, after a 3-yr pilot study • HTA is used to retrospectively assess whether the premium pricing is justified
China	• Increasingly integrating HTA into the healthcare system • However, it is still not fully embedded as a mandatory component

Source: APACMed and L.E.K. Consulting, 2020[11]

So where does this leave us? Clear need for a Digital Health valuation framework in the Asia-Pacific that serves as an input into appropriate funding and reimbursement policy.

Foundational concepts available from WHO, as well as legacy models like HTA. But still nothing that is adapted for policymakers in the region to balance the cost-benefit of medical-use Digital Health innovation nor to truly harness its potential as an enabler of healthcare and socioeconomic reform. Herein we propose the following set of dimensions to be considered in the assessment of Digital Health technologies, based on existing best practices from markets like the UK, Germany, France, and Korea that are already tailoring valuation to the bespoke needs of Digital Health (fig. 15):

Fig. 15 - Accessing the Value of Digital Health Technologies

Source: APACMed, 2020[6]

Of course, to adopt such a framework still requires context based on local market dynamics and structure. For example, in many countries there are two levels of payers – national reimbursement bodies and then hospitals, patients, or other such alternative funding mechanisms. Therefore, each type of payer may want to place different weight on the specified elements accordingly, while staying aligned to an overarching vision for Digital Health valuation.

"It is our view that 100% of Digital Health technologies should be covered, in line with our health equity philosophy," said Alison Verhoeven in Australia.

"Especially those technologies aimed at alleviating the expensive parts of the system. It is not sustainable to continue to publicly fund healthcare the way it is currently delivered. Beyond HTAs, we must look at PROMs (Patient-Reported Outcome Measures) and other social measures too. UHC is about leaving no one behind, so, we should prioritize the social licenses first, including for Digital Health technologies that are trying to make a real impact." Tikyani in India agrees with the sentiments, and therefore also suggests that any such valuation framework also have an

engagement strategy wrapped around it so as to ensure the ecosystem of stakeholders gets fully onboard with the concepts.

"If the clinical and economic value of the Digital Health is the same as the traditional medical device, then the coverage should be the same as well (in the case of Japan, usually 70%)," said Dr. Yosuke Hara, of Tohoku University School of Biomedical Engineering in Japan, who uses several Digital Health tools in his own practice and research. "But perhaps more important is to understand is that Digital Health actually enables full-scale economic evaluation in the field of preventative medicine, which is not often enough discussed in the medical care and the medical economy circles so far."

And while we believe the value assessment framework put forth for Digital Health technologies in the Asia-Pacific will help to address the fragmentation issues, value assessment alone is not enough. A holistic, fit-for-purpose model must go all the way through to funding. Current strategies amongst the Digital Health communities are to target existing reimbursement codes in order to enter the market, such as the space pumps, an infusion system, in Korea and Thailand that are reimbursed at the same rate, with no distinction made, as conventional pumps. Lack of Digital Health-appropriate coverage policy has led to a variety of monetization models, many of which we would consider to be "alternative pathways" and, while commercially viable, could potentially undermine broader healthcare and social reform programs in terms of overreliance on out-of-pocket expenditures, particularly for those population subsegments who risk falling back into poverty as a result.

Fig. 16 – Digital Health Monetization Models

Pay Per Use
For example, charging hospitals for every test that is performed (quite commonly reimbursed in the mature markets)

Upfront + Rental Fees
Especially relevant for solutions requiring regular maintenance, where the ongoing fee may represent 10-30% per period of the total contract value

Device + Consumables
"Razor and razorblades" model for solutions with expiring parts, typically a reimbursable payment for the users

Upfront + Subscription
Particularly useful for solutions with tiered offerings (e.g., premium customers with advanced functionality, usually scaled based on # users/utilization

Key Questions to Ask

- *Who are the targeted end users?*
- *What is the affordability level of the targeted end users?*
- *Who is expected to pay?*
- *What is the current level of competitive intensity?*
- *Purely digital or also involving devices, equipment, maintenance?*
- *Level of servicing required?*
- *What is the expected volume and frequency of usage?*
- *How regularly does the software need to be updated?*
- *What kind of differentiated software offerings can there be?*

Source: APACMed and L.E.K. Consulting, 2020[11]

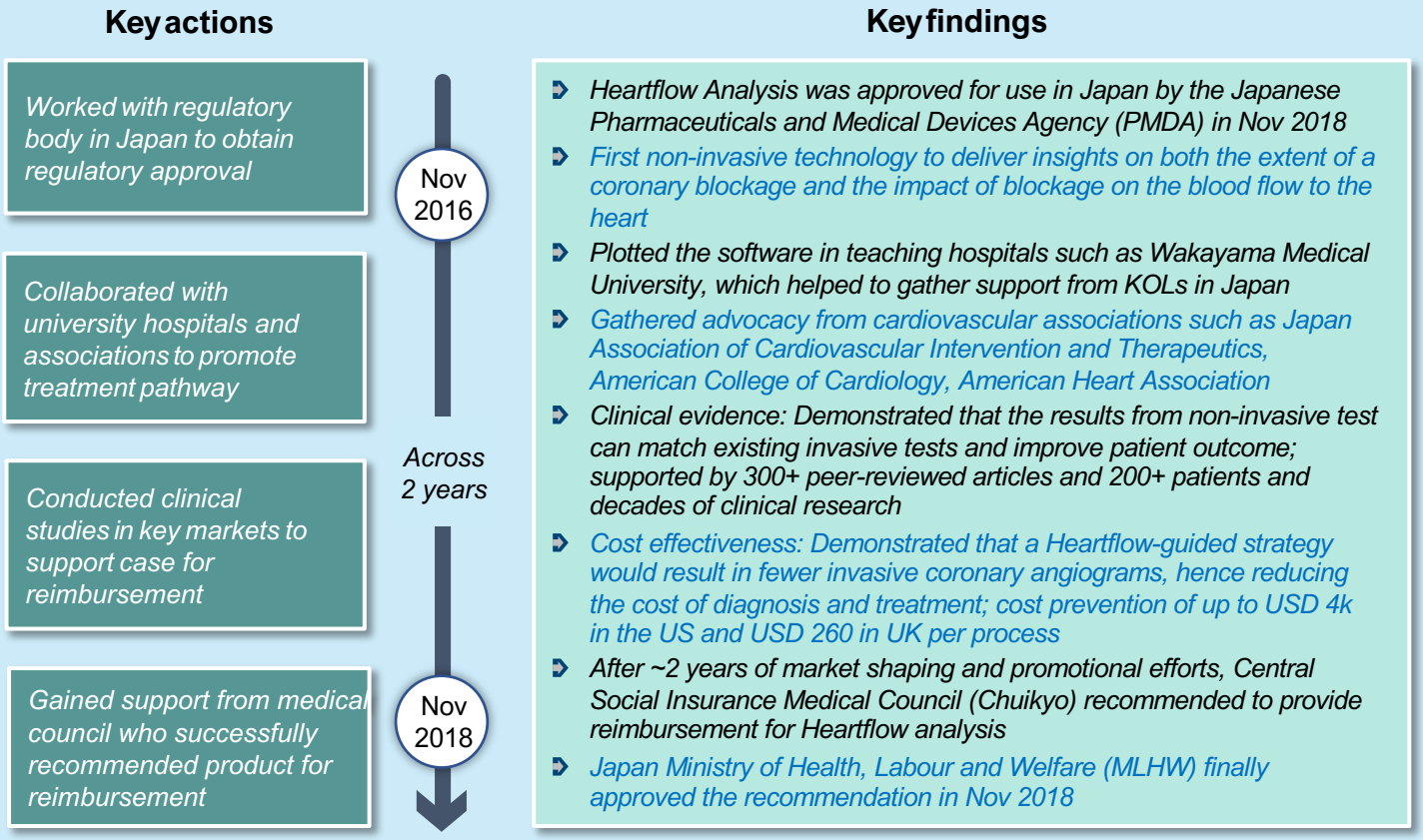
"The reality is that we are still looking at substitution for Digital Health reimbursement rather than full system transformation," said Verhoeven in Australia. "We need stronger governance in place, keeping a focus on the equity of the system." Dr. Marcelo in the Philippines echoed these sentiments, that expanding the existing reimbursement coding under UHC law for technology interventions is the near-term strategy for coverage. China has made headway with social insurance covering 95% of the population, now reimbursing for virtual follow- up consultations, digital chronic disease management, and online medication refills[6]. Local stakeholders expect these concepts to serve as a baseline for expansion into other related modalities in the near future. WeDoctor in addition to providing tech-enabled lifesaving reimbursed services to Wuhan residents during the pandemic, led a program in the Shandon province of 100 million people for remote patient monitoring that saw a 10% efficiency improvement in UHC founding utilization [6]. In Japan likewise, beyond the Heartflow analysis case study, as of November 2020 the first app for medical intervention is reimbursed, a smoking cessation tool considered a swap for outpatient clinic consultations

and that many believe paves the way for broader digitalized disease management coverage; indeed, the pipeline for reimbursed Digital Health technologies in Japan includes much-needed interventions such as for insomnia, depression, and diabetes. "It is necessary to align with government authorities at the early stages of product development about the medical categorization for Digital Health," said Tomiko Tawaragi, Chairman of the Council for Proper Use of Medicine in Japan, who pointed toward the recently submitted recommendation statement for Medical Device Reimbursement of software application by JAAME to the MHLW on behalf of the medical technology community.

Ultimately what we are talking about is a founding and reimbursement methodology that is more tailored to Digital Health technologies in Asia-Pacific. Not only does this serve the immediate need of gaining control over the Digital Health boom so as to ensure full alignment with broader healthcare and socioeconomic reform efforts, but moreover seeks to drive the future state ambitions of a more elastic, value-based system that is able to effectively balance the outcomes achieved (and measurements therein) against the cost of delivery. Connecting Digital Health value assessment and funding and reimbursement frameworks will finally unlock the true benefit for Asia-Pacific stakeholders. The HeartFlow Analysis case, as has been referenced throughout this paper, is an inspiring story that gives us hope for the effective harnessing of Digital Health technologies in Asia-Pacific, where its broader downstream value beyond just the reduction of direct costs of invasive diagnostics has been recognized and rewarded. Yet, the company's two-year journey and high evidence requirements point toward the remaining gaps and delays in equitable access to novel Digital Health innovations. So now it's a question of the ideologies therein, setting the right funding pathways that follow on the proposed logic of a Digital Health value assessment. As a final step, we introduce a fit-for purpose reimbursement framework for Digital Health in the Asia-Pacific, curated by APACMed and involving inputs from public/private stakeholders across the region. The framework is split across two country archetypes – Australia as a developed UHC market with predominately public payer model, and India rising to meet 4.0 ambitions with a tighter balance between public-private financing. Asia-Pacific policymakers reading this paper can select the archetype most closely aligned to their home structure, or of course pull the best from both.

Fig. 17 – HeartFlow's approach to gain reimbursement in Japan

As an example of best practices adoption, HeartFlow Analysis undertook a multi-step approach in Japan to successfully gain reimbursement



Source: APACMed and L.E.K. Consulting, 2020[11]

Fig. 18 – Policy Pathways for Harnessing the Potential of Digital Health

Archetype 1: Australia	Macro Socioeconomic Status	Macros Health System Status	Macro Digital Health Status
	• 25.6 million inhabitants • 15.9% aged 65+ • $57.4 thousand GDP/capita • 13.6% poverty rate • 99.0% literacy rate • 14th ease of doing business • 22nd innovation index • 86.5% internet penetration	• 9.6% GDP for healthcare • 87 UHC index • 67.3% healthcare is public • 3.7 doctors per 1,000 • 3.9 beds per 1,000 • 82.5 life expectancy • Cancer, CVD are top killers • 17% OPE for healthcare • HTA = established	• Definition on govt site • Blueprint/strategy themes: information availability, security, explainable data, medicines access, new models of care, empowered workforce, thriving innovation industry • Published cybersecurity guidelines

Digital Health Reimbursement (As-Is)	Digital Health Reimbursement (To-Be)
• Telehealth is 100% covered for all disease areas • 75% of the fee for remote cardiac monitoring services listed on the Medicare Benefits Schedule for private patients is covered by the Federal Government, and the 25% of the fee (or more if the doctor charges a gap) is covered by private insurance or by the patient out of pocket. In public sector, these services are very limited due to funding constraints and are funded through hospital budget • Reimbursement application can happen in parallel with regulatory approval • Reimbursement applications to generate fee for doctors' service (MSAC application) can be submitted by any stakeholder • Fee for service approvals for private sector may take up to two years for new procedures on the Medicare Benefits Schedule (MBS), with high evidence requirements for HTA. For existing code, prosthesis listing may take up to 8 months; for novel technologies requiring MSAC application, the listing may take up to 3 years on average • For existing code, prosthesis listing may take up to 8 months; for novel technologies that meet the Prostheses List criteria, the listing approval may take up to two years in parallel with the procedure approval on the MBS • However, reimbursement for Continuous Glucose Monitoring differs to that for MBS items: 100% federal subsidy to eligible people with diabetes for access to Continuous Glucose Monitoring (CGM) on the National Diabetes Services Scheme (NDSS) and may take up to two years for new CGM products to be listed on the NDSS, with high evidence requirements for HTA • No bespoke post-market surveillance	• Study effects of Digital Health during COVID-19 period • Beyond telehealth/monitoring, expand existing reimbursement codes to a wider range of Digital Health technologies • Settle on a value assessment model that is bespoke to Digital Health and not overly rigid like HTA • Investigate the spectrum of technologies and disease pathways that may most benefit from Digital Health • Start to create capacity for incorporation of new codes, specific to Digital Health • Ensure public and private sector alike are aligned on reimbursement, maintaining the vision of 100% coverage • Institute a more formalized PMS process, leveraging on Digital Health as a real-world data source • As Digital Health is deployed and data captured, align reimbursement to more novel contracting schemes (e.g., risk-sharing, MEAs, outcomes) • Re-evaluate the above to set clear go-forward criteria for Digital Health valuation, reimbursement by technology type and disease pathway • Seek to expedite timelines too, such as by establishing break-through designations for Digital Health, so as to match the innovation lifecycles

Archetype 2: India	Macro Socioeconomic Status	Macros Health System Status	Macro Digital Health Status

- 1.4 billion inhabitants
- 6.4% aged 65+
- $2.0 thousand GDP/capita
- 68.8% poverty rate
- 77.7% literacy rate
- 63rd ease of doing business
- 48th innovation index
- 34.4% internet penetration

- 3.6% GDP for healthcare
- 55 UHC index
- 30.0% healthcare is public
- 1.3 doctors per 1,000
- 0.5 beds per 1,000
- 69.2 life expectancy
- CVD, infection are top killers
- 65% OPE for healthcare
- HTA = in process

- Definition on govt site
- Blueprint/strategy themes: data infrastructure, open standards, EHR adoption, individual empowerment, federal/ state cooperation, medical research
- No published cybersecurity guidelines: however, dedicated committee formed

Digital Health Reimbursement (As-Is)	Digital Health Reimbursement (To-Be)

- Telehealth and remote monitoring are not clearly covered, though the situation is rapidly evolving in light of the COVID-19 needs
- Predominately allowing Digital Health proliferation through B2C channels, and/or private sector care providers and insurers who wish to establish new business streams
- For the regulated route, no clear distinction between Digital Health and a traditional medical device
- Complete medical device approval process overhaul – MDR, risk classifications, reciprocity recognition

- Incorporate Digital Health formally into the UHC ambition, including adjustments needed from COVID-19 observations
- Ensure the internal, external capacity for technology infrastructure and data exchange are at baseline
- Pilot the requirement of Digital Health to go through formal assessment process (e.g., starting with telehealth and remote monitoring)
- Reward the above through proper reimbursement, at least more than 50% so as to limit OPE burden
- Given the strong role of the private sector, anyway, allow private providers and payers to similarly pilot reimbursement/ co-pay models of their own
- Formalize the above by distinguishing medical device assessment/reimbursement models from those tailored for Digital Health, with specificity by tool and disease type
- Emphasis on use of existing reimbursement codes for Digital Health, though planning longer-term for new codes
- Use the real-world data collected to continually monitor and improve the frameworks
- As the health system and literacy mature, begin to think about novel contracting models that are fit-for-purpose for Digital Health
- Over time, decrease the indirect coverage models in favor of a true UHC vision

> I see the situation as two-time horizons – near-term adoption of break-fix ideas, and a longer-term build-out of new pathways and schemes for Digital Health, the former feeding into the latter," said McMahon in Australia. "Ultimately the vision is to connect the Digital Health solutions into the coordinated care delivery models, and to evolve our contracting into more of a value-based, data-driven decision-making process. Not just funding Digital Health as a widget, rather as a much-needed behavioral change program for our health systems. We are only at the beginning of the hype cycle, proper incentives and collaborations must be put in place.

The above is a guiding Digital Health reimbursement framework proposal, connected to the value assessment model. It will take more time and discussion to build these out at scale in the Asia-Pacific, including the evidence generation and refinement therein.

APACMed and its members are up to the challenge, we look forward to working together on the journey. The last section of this paper outlines an actionable checklist for getting started.

07 The Path Forward

We appreciate the opportunity to share the frameworks provided above for value assessment and reimbursement pathways of Digital Health technologies in the Asia-Pacific, including with the gracious inputs of public and private stakeholders in the region who are equally passionate about driving progress in this area. We look forward to ongoing discussions for improving and aligning these frameworks, so as to ensure they do not gather dust on a shelf but, instead, become integrated into standard health system governance programs.

"Funding and reimbursement are key policy strategies to ensure the ROI of population investments," said Wong in Singapore. "We may need a policy stick to start and a carrot to keep going, and we should view Digital Health technologies as a core mechanism toward becoming overall smart nations." Asia-Pacific policymakers can look at Germany's recent move to approve and reimbursement Digital Health for 12 months in order to allow sufficient time for evidence generation, then make a decision about ongoing coverage and pricing for scale-up.

It will be a learning journey for all of us. The Digital Health "boom" has arrived, particularly in the post-COVID-19 era. Developed and developing countries alike in the Asia-Pacific must adopt next-gen health and care strategies that empower, not undermine, broader socioeconomic ambitions. At APACMed, we believe a key ingredient lies in Digital Health and the Digital Patient. This requires a fit-for-purpose approach that is neither too loose nor too stringent for the technologies. Greater coverage policy is therefore needed in order for countries to realize the derived value in Digital Health access, outcomes, cost-effectiveness, and funding transparency in this evolving area. The landing of the HeartFlow Analysis innovation into Japan is no coincidence – medical technology launch location selection follows closely the readiness and reimbursement pathways of the host country, a self-sustaining philosophy.

So, Asia-Pacific policymakers have a fork in the road – allow Digital Health to proliferate through under-controlled channels and potentially fail to harness its potential or shift from good-to-great by taking proactive measures to put appropriate structure around the situation, including by leveraging Digital Health to address the disparity and inequality of healthcare access. Clearly the latter is recommended by this paper and APACMed constituents, and we are here to help.

Fig. 19 – Post reimbursement: Expected Increase in Usage

Source: APACMed and L.E.K. Consulting, 2020[11]

> "Reimbursement is a key policy strategy to ensure the ROI of population investments," said Scott Wong in Singapore. "We may need a policy stick to start and a carrot to keep going, but we should view Digital Health technologies as a core mechanism toward becoming overall smart nations."

In order to make true on the value assessment and funding and reimbursement frameworks, we provide the following action plan for policymaker consideration (fig. 20).

Fig. 20 – Proposed Action Plan for Policymakers

Step 1
Situational Analysis

- Establish a Digital Health-specific categorization that is in line with international standards and clearly distinguished from the traditional medical devices.
- Determine the baseline size of disparity and inequality in the health system, thereby framing the potential opportunity for Digital Health impact.
- Map to one of the archetypes provided above – it may not be an exact fit, but the spirit behind the two options should be well-intended.

Step 2
Planning

- Formally incorporate Digital Health into national planning cycles, with an aim to adopt a bespoke approach to fit-for-purpose funding and reimbursement.
- Create a multi-stakeholder taskforce across public and private sector, including with a mechanism for international best practices sharing on Digital Health.
- Identify local champions (government, doctors, patients) who can serve as role models in ushering in the wave of Digital Health reimbursement models.

Step 3
Execution and Adoption

- Publish a clear roadmap, milestones to achieve the above, with articulation of how Digital Health reimbursement delivers the socioeconomic returns.
- Publish a clear roadmap, milestones to achieve the above, with articulation of how Digital Health reimbursement delivers the socioeconomic returns.
- Implement an ongoing monitoring process to ensure the benefits of the program are realized, and any pivoting needs therein are addressed.

"We must appropriately assess, value, and fund Digital Health technologies while remaining true to our fundamental principles of UHC," said Verhoeven in Australia. "We must ensure that technology and social structures move at a lock- step pace so as to retain a balance between the financing deployed and the health outcomes achieved."

"APACMed can help play a leading role in the discussion by informing governments about the latest advancements in technology"

said Dr. Kim in Korea. "Sometimes we lack visibility and cannot react quickly enough. Thus, a true public-private partnership is needed for Digital Health adoption."

08 Authors and Contributors

Authors

Chris L. Hardesty Global advisor for healthcare ecosystem innovation, chrishardesty@kpmg.com.sg

Roberta Sarno, Digital Health Manager, APACMed, rsarno@apacmed.org

Anh Bourcet, Chair of the APACMed Digital Health Committee Reimbursement Workgroup | Director ASPAC, Health Economics and Market Access, Johnson & Johnson

Arif Fahim, Regional Director – Asia Pacific, Health Economics & Reimbursement, Abbott

Jaehyun Suh, Market Access Specialist, Bbraun

Julianna Yeung, Senior Manager, Strategic Care Coordination, Fresenius Medical Care

Michael Nobes, Market Access Director, Abbott

Michiko Nishimura, Head – Health Economics & Reimbursement, Abbott Japan

Ranu Khakhalari, Market Access Analyst – Asia Pacific, Abbott

Sebnem (Shebnem) Erdol, Head – Health Economics & Reimbursement, Abbott ANZ

Shweta Bhardwaj, Associate Director, Global Policy, Johnson & Johnson

APACMed Digital Health Committee Members

Interviewed Stakeholders

Alison Verhoeven, Australian Healthcare and Hospitals Association CEO (Australia)

Alvin Marcelo, St. Luke's Medical Center IT SVP and CMIO (Philippines)

Ataru Igarashi, University of Tokyo Dept. of HEOR Visiting Associate Professor (Japan)

Bettina McMahon, Australasian Institute of Digital Health Chair (Australia)

Imelda Corros and Pilar Teves, KPMG Healthcare and Life Sciences (Philippines)

Joo Youn Kim, National Evidence-Based Healthcare Collaborating Agency (Korea)

Sangeeta Tikyani, Dr. ASK Healthcare at Home Public Health Director (India)

Scott Wong, Ng Teng Fong General Hospital Medical Officer, under MOHH (Singapore)

Sebastien Gaudin, CareVoice CEO (China)

Timothy Johns, UK Department for International Trade Digital Health Head (China)

Tomiko Tawaragi, Council of Proper Use of Medicine Chairman (Japan)

WeDoctor (China)

Yosuke Hara, Tohoku University and LIFE TODEI CEO (Japan)

Acknowledgements

Arathi Sasidharan, Principal, L.E.K. Consulting

Stephen Sunderland, Partner, L.E.K. Consulting

09 References

1. "Sustainable Healthcare in APAC: Financing and Delivery Models". World Economic Forum (2020).
2. World Bank Database (Various Modalities): https://data.worldbank.org/ Accessed Dec 2020.
3. APACMed-KPMG MedTech Industry Footprint Presentation (2019). https://apacmed.org/medtech-industry-footprint-presentation-2019-kpmg/ Accessed Dec 2020.
4. "Challenges for the evaluation of digital health solutions—A call for innovative evidence generation approaches." Guo C., Ashrafian H., Ghafur S., Fontana G., Gardner C., Prime M. Nature Partner Journals, Digital Medicine (2020). 3:110 https://doi.org/10.1038/s41746-020-00314-2
5. "COVID-19 Consumer Survey". McKinsey & Company (2020, Apr 27).
6. APACMed Primary Research Activities (2020) https://apacmed.org/our-work/digital-health/ Accessed Dec 2020.
7. "Artificial Intelligence: Healthcare's New Nervous System" WTN News, Accenture Consulting (2017). https://wtnnews.com/2017/09/26/artificial-intelligence-healthcares-new-nervous-system/ Accessed Dec 2020.
8. "3D Printing in Healthcare – Where Are We in 2019?". AMFG (2019). https://amfg.ai/2019/08/30/3d-printing-in-healthcare-where-are-we-in-2019/ Accessed Dec 2020.
9. "Digital Health: A Framework for Healthcare Transformation". HIMSS (2020). Accessed Dec 2020.
10. "Assessing the Impact of Digital Transformation of Health Services." Report of the Expert Panel on effective ways of investing in Health, European Commission (2019).
11. Navigating the Digital Health Reimbursement Landscape in Asia-Pacific." APACMed and L.E.K. Consulting (2020). https://apacmed.org/our-work/digital-health/ Accessed Dec 2020.
12. "Asia-Pacific Has Some of the World's Most Connected, Mobile, and Social Digital Users". AiThority (2019). https://aithority.com/mobile/asia-pacific-has-some-of-the-worlds-most-connected-mobile-and-social-digital-users/ Accessed Dec 2020.
13. "Sustainable Healthcare Investment as an Economic Driver: The Time for ASEAN to Act Is Now." KPMG (In Collaboration with Sanofi and EU-ASEAN Business Council) (2020, Mar 9).
14. World Health Organization Database (Various Modalities). https://www.who.int/data Accessed Dec 2020.
15. "WHO Guideline: Recommendations on Digital Interventions for Health System Strengthening". World Health Organization (2019).
16. "People in Singapore Spend Over 12 Hours on Their Gadgets Daily". The Straits Times (2017). https://www.straitstimes.com/singapore/12hr-42min-connected-for-hours Accessed Dec 2020.
17. "Trends in the Adoption of Robotic Surgery for Common Surgical Procedures". Sheetz KH, Claflin J, Dimick JB. JAMA Netw Open (2020). 3(1):e1918911. doi:10.1001/jamanetworkopen.2019.18911
18. "Digi-HTA: Health Technology Assessment Framework for Digital Healthcare Services". Haverinen J., Keränen N., Falkenbach P., Maijala A., Kolehmainen T., Reponen J. Finnish Journal of EHealth and EWelfare (2019). 11(4), 326–341. https://doi.org/10.23996/fjhw.82538
19. "How to Value Digital Health Interventions? A Systemic Literature Review". International Journal of Environmental Research and Public Health. 2020. Kolasa K., Kozinski G. International Journal of Environmental Research and Public Health (2020 Mar). 17(6). DOI: 10.3390/ijerph17062119
20. "Modernizing Medicare Coverage of Digital Health Technologies". AdvaMed Centre for Digital Health. (2020 Sep) https://www.advamed.org/sites/default/files/resource/advamed-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf Accessed Dec 2020.
21. "Suitability of Current Evaluation Frameworks for Use in the Health Technology Assessment of Mobile Medical Applications: A Systematic Review". Moshi MR, Tooher R, Merlin T. Int J Technol Assess Health Care (2018 Jan). 34(5):464-475. doi: 10.1017/S026646231800051X. Epub 2018 Sep 11. PMID: 30201060.

About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. In 2020, APACMed established a Digital Health Committee to support its members in addressing regional challenges in digital health.

For more information, visit: www.apacmed.org

2 Science Park Drive
Ascent Tower, #02-03
Science Park 1
Singapore 118222
T(65) 6816 3180