



Special Report

Health Services in APAC — Opportunities, Challenges and the Path to Progress: Insights From Medtech

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Foreword



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Asia Pacific Medical Technology Association (APACMed)

The medical technology (medtech) industry has historically been considered a manufacturer of products. However, increasingly, medtech companies are delivering health services and solutions to complement their core product offerings and deliver end-to-end patient care. Nonetheless, there has been limited awareness of such services, and more importantly, funding of these solutions is fragmented.

Against the backdrop of the increasing prevalence of noncommunicable diseases, aging populations, an emerging middle class demanding higher-quality care, and significant healthcare infrastructure and resourcing challenges across the Asia-Pacific markets, it is important for governments and the private sector to work together to facilitate diversified provision of, and increased access to, high-quality, value-based care to meet the growing healthcare needs of the region.

At APACMed, our mission is to provide a unified voice for the medical technology industry in the Asia-Pacific (APAC) region — to improve standards of care for patients and strengthen healthcare ecosystems across APAC through promoting access to the highest quality of healthcare for patients, demonstrating the value of innovation and promoting regulatory harmonization.

Therefore, in July 2021, APACMed members formed a new Health Services Working Group to support providers, policymakers,

payors and patients in understanding the emerging health services landscape delivered by medtech.

This paper, *Health Services in APAC — Opportunities, Challenges and the Path to Progress: Insights From Medtech*, published in collaboration with L.E.K. Consulting, provides a comprehensive overview of the landscape of the health services market with key insights from executives across the ecosystem.

Using an archetype approach of four categories and supported with interviews with various experts and best practice case studies, this paper provides a framework to map the evolving landscape of innovative health services delivered by medtech and identify key opportunities where provision of quality health services and systems in the region may be improved.

I am glad there is much opportunity for collaboration across stakeholders to deliver true patient-centric care and benefits to the healthcare system. Collaboration with various stakeholders is at the core of APACMed's patient-centric mission. Beyond this paper, I welcome the opportunity to discuss with industry partners, payors, policymakers and patients the importance of health services and the opportunities to be unlocked in partnership with medtech companies in the next phase. APACMed looks forward to the insights from these upcoming engagements and will continue to work in partnership with governments and stakeholders to strengthen health services and systems in the region.

Executive summary

MedTech-delivered health services

The medtech industry has excelled at producing cutting-edge medical devices, therapeutics and health technologies for decades. There is now a growing recognition of the need to directly drive and enable innovation in the delivery of health services in order to maximize the efficiency, capacity and responsiveness of healthcare systems. Medtechs are expanding their clinical care delivery service offerings, which this paper categorizes into four types: (1) clinical education services — upskilling of physicians and empowering patients, (2) care coordination services — end-to-end care provision using digital technology, (3) clinical operation and analytics — clinical decision support using medtech data analytics and (4) direct-to-patient clinical services — care delivery sites, fully owned or in partnership with healthcare providers.

Barriers to medtech health services

The adoption of medtech-supported clinical care delivery services faces significant barriers, including limited reimbursement provisions, unclear legal frameworks and onerous data privacy regulations. Low awareness of the potential benefits of health services results in missed opportunity for public-private partnerships and low utilization of the clinical data generated by medtechs. These barriers are evident across APAC, including Australia, China, Japan and Korea, although each country has its own specific and additional considerations. Despite challenges, a number of medtechs — through persistence, evidence-based

persuasion and astute partnering — have demonstrated best practices in driving service adoption, reviewed as case studies in this report. The medtech industry, using these best practices, can effectively engage and partner with the various stakeholders to ensure the provision of quality health services.

Change agents

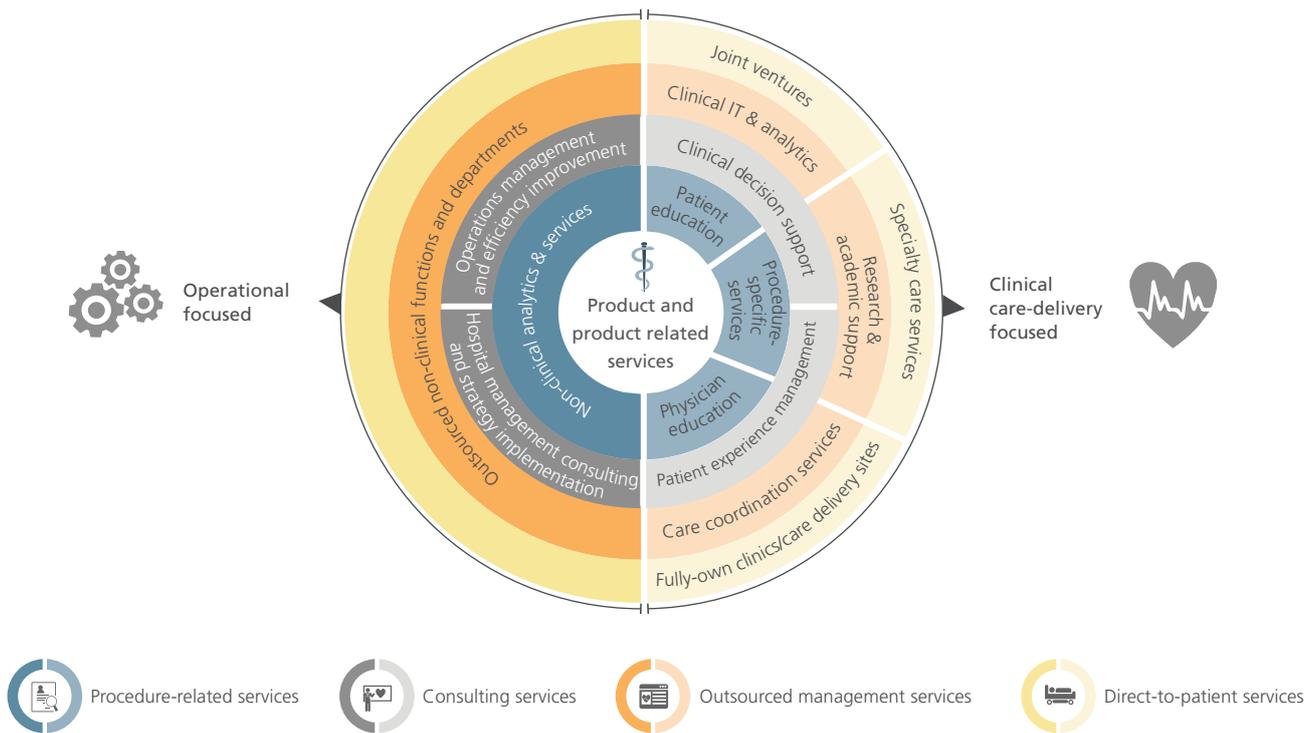
Proactive **policymakers** play a critical role in galvanizing change, setting the incentives for permanent shifts to more effective patient care through the adoption of innovative services. Policymakers could establish open communication with industry partners and facilitate balance in the perceived trade-offs between patient privacy and the value of data analytics.

Institutional payors could ensure greater flexibility in financing innovative services currently limited by reimbursement systems/ payment processes that largely confine reimbursement to acute care institutions. This would incentivize healthcare providers to innovate care delivery models and deliver superior care at a greater value.

Healthcare professionals (HCPs) should view medtech health services as complementary catalysts for improved patient access, better outcomes and more cost-effective care. Working collaboratively with medtechs in co-development or risk-sharing agreements would facilitate the involvement of industry stakeholders, strengthening the process through the introduction of global expertise and best practices.

Introduction to the health services landscape

Figure 1
Medtech-delivered health services landscape



1. Medtech’s evolution to deliver health services

Medical devices are instruments, apparatus or machines used in the prevention, diagnosis or treatment of illness or disease.¹ Medtech can be defined as the technologies that diagnose, treat and/or improve a person’s health and well-being, encompassing both low- and high-risk medical devices.²

The medtech industry has excelled at producing cutting-edge medical devices, therapeutics and health technologies for decades. In recent years, the role of medtech has evolved from offering medical devices and products to also providing a range of value-added clinical and operational services that complement effective healthcare delivery (see Figure 1). With growing recognition of unmet needs in specific patient groups, providers and populations, medtechs have stepped up into the provision of services to maximize the efficiency, capacity and responsiveness of healthcare systems. Figure 1 lays out the landscape of how

medtech companies, in a health service provision role, operate in four different services categories. Today, many medtech companies deliver services to healthcare providers, often free and not separately charged.

Given the increase in the prevalence of noncommunicable diseases, an aging population and an emerging middle class demanding higher-quality care in the APAC region, there is a clear need for leveraging the deep, global expertise of medtechs to augment and accelerate the development of health service provision in health systems across APAC; those systems are at varying levels of maturity in different markets. Working at scale, medtechs have developed a variety of innovative solutions for healthcare providers such as innovation in clinical practices and data-driven solutions to support better clinical outcomes, as well as extending the care continuum beyond traditional acute care settings.

Beyond healthcare providers, medtech-delivered services can drive clinical, socioeconomic and system-level benefits for various

stakeholders, including payors, healthcare providers, HCPs and patients (see Figure 2 below).

While the value proposition of medtech-delivered services is clear, the acceptance and adoption of service delivery innovations need to be improved. We believe there is significant opportunity ahead to scale adoption of these services. These opportunities, as well as barriers to overcome, are explored in greater detail in this paper.

2. Medtech’s new frontier: health services

Medtech has produced highly innovative medical devices, therapeutics and health technologies enabling more precise and effective diagnosis, monitoring and treatment. Similarly, medtech companies have applied their innovation capabilities into the domain of service delivery as well. Innovative care delivery services such as Medtronic’s CareLink implanted heart remote monitoring system³ (allowing for early and prompt detection of abnormal heart rhythms/device issues), Abbott’s NeuroSphere virtual clinics⁴ (alleviating chronic pain or movement disorders for patients without access to a physical care provider), Baxter’s ShareSource remote patient monitoring software application (helping monitor

patients remotely on “Home Dialysis — PD” and reducing the risk of being exposed to COVID-19), and Hillrom’s RetinaVue solutions⁵ (enabling HCPs to incur one-third the previous cost for retinal imaging). Such medtech-led clinical care solutions come at a propitious time for APAC. The region’s COVID-19-distressed healthcare systems face significant unmet needs in clinical delivery, including HCP shortages, insufficient hospital bed capacity and inequitable access to healthcare facilities and services.⁶

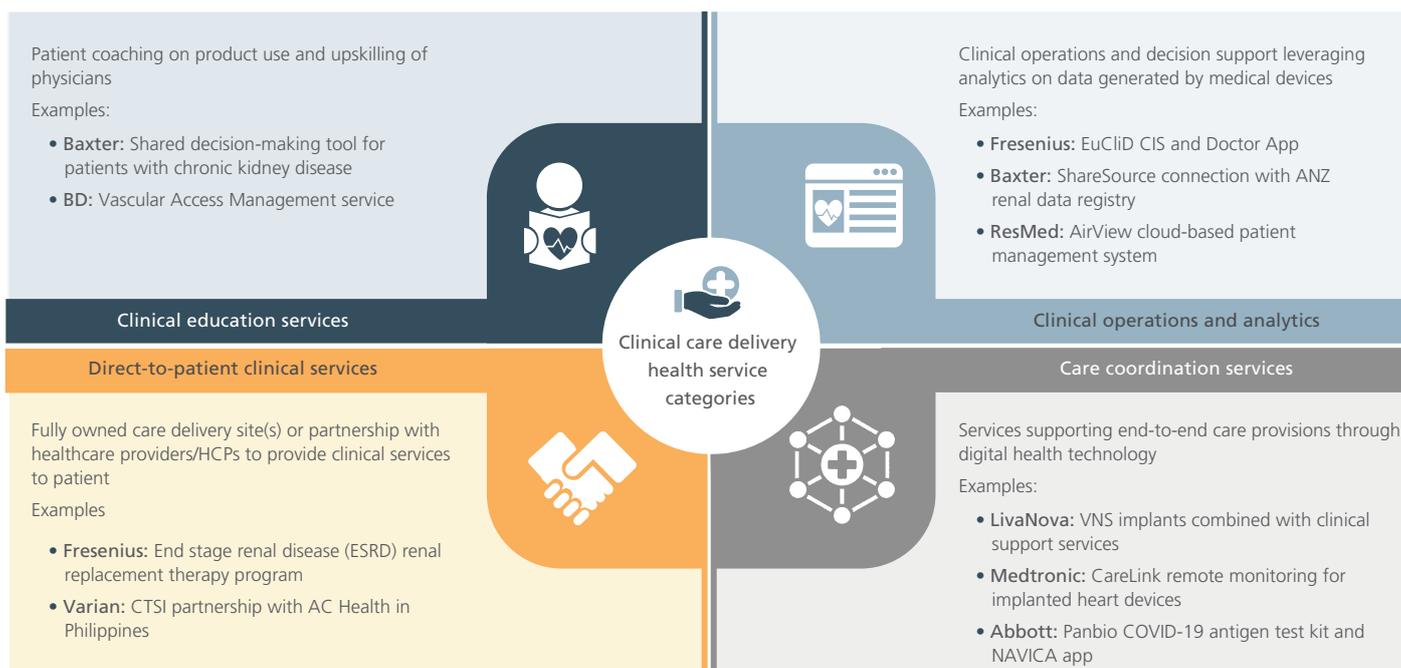
Unfortunately, in many countries across APAC, the adoption of medtech-supported clinical care delivery services faces significant barriers. These include challenges around limited reimbursement provisions, unclear legal frameworks and onerous data privacy regulations. There are also opportunities to improve health systems if medtechs can leverage public-private partnerships and utilize the valuable clinical data and analytics generated from health services.

For the remainder of this paper, clinical care delivery health services will be categorized into four types of services (see Figure 3): (1) clinical education, (2) care coordination, (3) clinical operation and analytics, and (4) direct-to-patient clinical.

Figure 2
Value-added medtech-delivered health services accrue to all key stakeholders

	Healthcare provider	HCP	Institutional payor	Patient
Clinical value	Greater numbers of patients served with expanded care settings	Optimal care provision to patients via improved communication and coordination	Opportunities to evolve reimbursement framework for innovative clinical treatment settings	Greater access to HCPs without geographic limitations
Socio-economic value	Improved care transition and hospital resource use	Embedding of best practices and upskilling of HCPs with innovative procedures	Cost savings from reduced wastage and better patient outcomes	Improved QALY with greater prospects of improved treatment outcomes
Others	Outsourcing opportunities of specific care areas	Increased clinical and operational efficiencies through analytics of device-generated data	Increased utility of data and analytics for evidence generation and policy shaping	Empowerment of patients in self-care, supporting treatment adherence and faster recovery

Figure 3
Medtech clinical care delivery health services defined

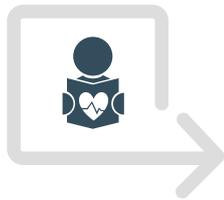


In the sections that follow, the paper will explore each category of clinical care delivery services, laying out their definition, challenges and opportunities for wider adoption, including solutions/

best practices. This is followed by a section that discusses the corresponding implications for policymakers, payors and providers.

Clinical education services

Figure 4
Clinical education services



Provider education

- **Continuing HCP education** (e.g., Univadis offering international training courses or interactive online courses)
- **Clinical procedure training** (e.g., Da Vinci robotic surgery SimNow training program to train surgeons using robotic-assisted surgery)
- **Clinical practice improvement** (e.g., BD VAM program)



Patient education

- **Treatment options education** (e.g., Baxter's My Kidney Journey website to inform patients on treatment options for CKD)
- **Inpatient & post-discharge education services** (e.g., wound care management, self-care training)
- **Outpatient or home care support** (e.g., BD diabetes care management app)

Clinical education services are a critical, but often neglected, component of effective care delivery. For patients, clinical education services help augment the efficacy of existing treatment modules and improve inpatient and post-discharge treatment adherence management. Empowered patients are also equipped to engage in shared decision making with their clinical team for appropriate care. For providers, clinical education services encompass continuing education for HCPs, clinical procedure training and clinical practice improvement. Therefore, medtech-delivered clinical education services can be segmented into those services that support providers and those that support patients (see Figure 4).

The rollout of clinical education services in APAC is often impeded by several interconnected issues, including (1) the need for unbiased content, (2) better recognition of medtech investment in training centers, (3) greater acceptance of these services by patients and physicians, and (4) the need for advanced information and communications technology (ICT) infrastructure.

1. Need for unbiased content. In many APAC countries, there is a persistent bias against medtech-delivered patient and provider education services; the thinking is that they exist purely for promotional and commercial interests. Patients, payors and institutional users unaccustomed to the delivery of services by such private solutions providers are less able to quantify the intangible benefits of patient/clinician education support frameworks. Instead of medtechs solely driving the services, some of the perceived bias could be alleviated by involving multiple stakeholders to simultaneously facilitate

clinician and patient education. One such example would be Baxter's shared decision-making tool used in Japan, which provides a common platform to mediate communication between various stakeholders involved in clinical decision making⁷ (elaborated further in case study [below](#)).

2. Recognition of medtech training center investment.

Investing in new healthcare facilities may often be viewed more favorably compared to the provision of new services, even when the service initiative aligns with government priorities such as upskilling and better care delivery. Respected medical associations' involvement may be needed to reinforce medtech service providers' credibility. Such was the case with the dedicated renal care training hub established by Fresenius in South Korea, which was supported by the Korean Society of Nephrology.

3. Greater acceptance of medtech services. Other than traditional clinical education, the medtech industry also provides services that can help improve clinical practice. However, there is a perceived notion of medtech having a vested interest in selling products or solutions through the service. To overcome this perception, medtechs can demonstrate the value of clinical services in terms of clinical outcomes, socioeconomic benefits or both. An example is BD's development of its Vascular Access Management (VAM) service using an evidence-centered approach.⁸ BD developed the VAM service to help hospitals identify opportunities for vascular access clinical practice improvement, and its value has been assessed in several performance metrics across 300 different parameters (elaborated further in case study [below](#)).

4. Need for advanced ICT infrastructure. With a shift of care to the community and at home, medtech has developed new services and tools to support the new care model. BD's Diabetes Care mobile application provides education to diabetes patients on insulin injection techniques that are

critical for optimizing care outcomes.⁹ Other than mobile apps, there are opportunities for more patient and physician education platforms through augmented reality, virtual reality and simulation-based training.

Case study: reimbursement for CKD shared decision-making is approved in Japan

The concept of shared decision-making (SDM) is relatively new to Japan; chronic kidney disease (CKD) is not. The number of cases continues to rise, and the cost of hemodialysis (HD) therapy currently accounts for 5% of total medical expenditure in Japan.¹⁰ Dialysis severely impacts patients' day-to-day life experience for decades or longer. Japanese CKD patients deserve a stronger voice and more significant input into therapy choices.

In Japan, there are three main CKD treatment options:

1. Kidney transplant — a relatively rare procedure in medically sophisticated Japan due to legal issues around confirming brain death, as well as religious concerns
2. Peritoneal dialysis (PD) — despite its psychosocial advantages for patients who are employed or generally wish to remain active, the number of PD patients in Japan is the lowest in the developed world (2.7%).¹¹
3. Hemodialysis (HD) — the dominant therapy and the standard recommendation of Japanese doctors (97%)

Value: There is a need to develop cost-effective and accessible dialysis modalities that offer improved patient outcomes — as defined by the patient. SDM for the renal replacement solution is an important tool for including the patient's perspective. The number of PD patients has been gradually growing since 2016, albeit from a low base. A recent survey suggests strong latent demand, with around 40% of CKD patients¹² indicating they would prefer to have PD at home or at night. As seen elsewhere, Japanese patients value longevity, but reducing the symptom burden and achieving maximum functionality and social rehabilitation are also priorities.

Barriers and strategies to overcome barriers: The Japanese reimbursement system is very complicated. Technical fee reimbursement applications can be submitted only by medical associations. Baxter was fortunate to find a forward-thinking

medical association, the Japanese Society for Dialysis Therapy (JSDT), and they worked together to introduce the SDM concept into dialysis therapy reimbursement. Fortuitously, a kidney support association survey that revealed growing patient preference for PD helped make the case. Despite a lack of clinical evidence to support the SDM concept, the JSDT and the Ministry of Health, Labour and Welfare (MHLW) reached an agreement to realize reimbursement for SDM as a proof of concept. In the 2018 reimbursement revision, MHLW created an evaluation system for SDM.

A so-called introduction premium was given to healthcare institutions for a one-month period, with the SDM evaluation being conducted by doctors or nurses — a 30-minute consultation presenting the choice between HD, PD and transplant. Designed to encourage PD uptake, the introduction premium is applicable only to new HD patients. Healthcare institutions that use PD, or have the capability to use PD, are given a slightly higher introductory premium (¥4,000/therapy/patient for the first month) as an additional incentive.

PD uptake has improved since 2018, but many doctors and hospitals remain hesitant, and in 2020 the program was revised to make it more attractive (¥5,000/therapy/patient for the first month). Most Japanese healthcare institutions are still HD only; some do both HD and PD, but very few do PD only. This is a more intractable infrastructural impediment to PD adoption. It is impossible to introduce PD to patients who prefer a hospital that offers HD only. Patient and HCP unfamiliarity with HD is the root problem.

SDM, whether in the context of CKD, cancer treatment or other chronic illnesses such as Parkinson's, should gradually gain acceptance. In Japan, awareness and confidence building with key medical associations and government agencies are vital elements of ongoing advocacy. Baxter reports increased requests from hospitals to train their dialysis care providers in PD, and the number of hospitals that use PD has increased to around 1,000 over the past 10 years.

Case study: BD's Vascular Access Management service

Vascular access is one of the most frequently required invasive procedures for hospitalized patients, with studies showing between 60% and 90% of inpatients receiving an IV.¹³ Despite how frequently the procedure is performed, it is associated with a high failure rate — with 40% of peripheral cannulations failing on the first attempt¹⁴ and between 35% and 50% of peripheral intravenous catheters (PIVCs) failing before their full dwell time, largely due to complications.¹³ A variety of complications can arise from vascular access, with the most severe infections — central line-associated bloodstream infections — having the potential to add an average of 16.8 days to a patient's length of stay.¹⁵

Value: BD's VAM service is an integrated, evidence-based approach to vascular access preparation, placement, care and maintenance in which BD partners with customers to assist in their efforts in improving practice. The process starts with an audit, which for a larger hospital takes about a week, with BD deploying multiple nurse educators to work with hospital counterparts in interviewing clinicians and patients, observing clinical practices, and assessing in situ lines for risks. The audit collects data on over 300 different parameters to derive a series of recommendations that are based on best practice guidelines from local or international organizations

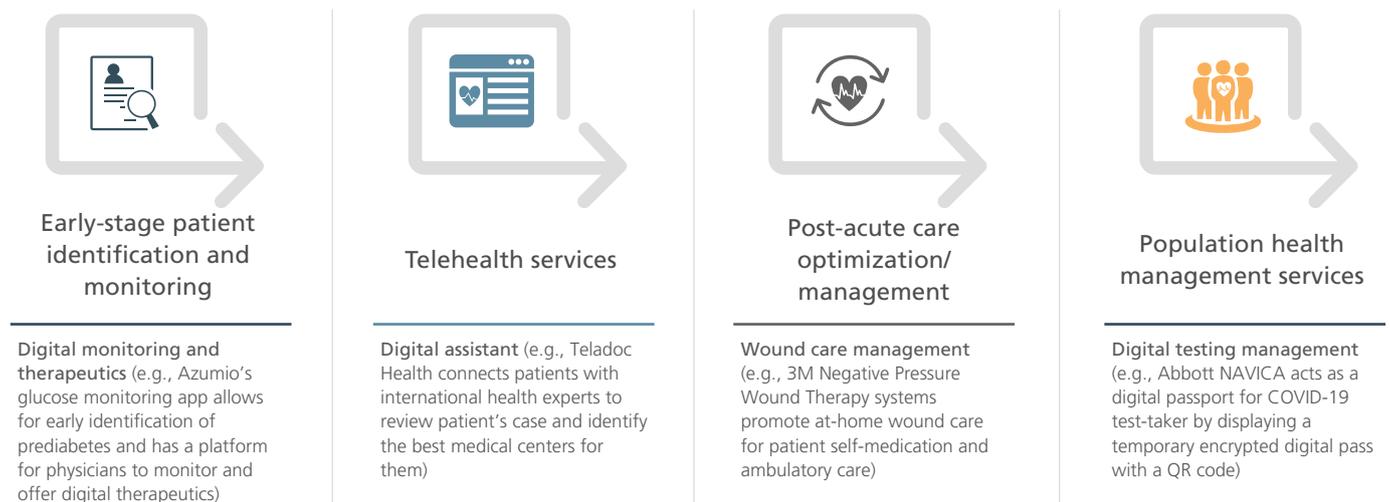
(e.g., the Australian Commission on Safety and Quality in Health Care or the Infusion Nurses Society). From 2014 to 2016, the University of Florida Health Jacksonville followed up two years from the implementation of the PIVC process improvement program and found significant improvements in process, safety and clinical efficacy.¹⁶ For instance, the incidence of unused extension sets was reduced by 86%; blood spillage or leakage was reduced from 50% to 0; the number of successful first attempts for PIVC insertion nearly doubled, which means reduced puncture attempts and fewer adverse experiences for the patients; an 80% increase in mean catheter dwell times, which led to a reduced number of catheters needed during a patient's average hospital stay (approximately seven days) by 33%; and so on.¹⁶

Barriers: While hospitals and clinicians recognize the importance of audit services to provide objective assessment of the procedures when offered by medtech companies, those companies are sometimes perceived as having a vested interest in selling products or solutions through the service.

Strategies to overcome barriers: Given the general value and importance to hospitals of reducing VAM-related complications, BD leverages proof points from existing partners to demonstrate the value of the service and ensures its recommendations are not focused on product substitution.

Care coordination services

Figure 5
Care coordination services



Fragmented locations of care and diverse patient care pathways — across multiple locations or facilities, with each pathway unique to each patient — drive a need to systematically coordinate, track and monitor patients. Care coordination services (see Figure 5) include early-stage patient identification and monitoring, telehealth services (including remote patient monitoring), post-acute care management involving post-discharge monitoring, and population health surveillance/management to enable prompt response by national-level clinical teams.

Healthcare services aim to facilitate seamless, end-to-end care provision between healthcare providers and patients across the continuum of care (from prevention to post-care management) in different settings along the patient's journey. However, medtechs face multiple obstacles to their participation in the delivery of care coordination services. To accelerate the development of cost-effective care coordination services for sustainable healthcare systems across APAC, there is a need to (1) recognize care coordination services for reimbursement, (2) establish clearer and more open legal frameworks and (3) shape a conducive and collaborative environment for participating in public-private partnerships (PPP).

1. Limited reimbursement provisions. Across many APAC healthcare jurisdictions, medtechs face limited reimbursement provisions for supportive care services. This causes a lack of clarity on payment modes leading to suboptimal adoption of care coordination services. Strained economic circumstances in many APAC countries have placed greater emphasis on the clinical and socioeconomic returns of proposed services

in support of the case for reimbursement (e.g., metrics such as hospitalization rates, length of stay, mean savings and the overall impact on hospital resources once care coordination services are in place). In Korea, the government does not provide reimbursement for telemedicine or remote patient monitoring; however, Baxter's remote patient monitoring software, ShareSource, was able to get a temporary reimbursement during the COVID-19 pandemic to minimize the exposure of dialysis patients to COVID-19 because their home peritoneal dialysis is monitored remotely through the software. Where governments and payors are open to persuasion, demonstration of the social and economic benefits can be compelling. LivaNova's budget impact study in Japan revealed US\$85 million in cost savings from the optimization of the treatment flow of drug-resistant epilepsy (DRE) patients.¹⁷ Evidence of potential benefits acts as a driver for a new referral system expected to be introduced by MHLW wherein surgery-eligible DRE patients can be timely referred to neurosurgeons, ultimately resulting in improved treatment outcomes. However, for other products/regions, LivaNova continues to strive for reimbursement for its Connect patient data management system (elaborated further in case study [below](#)).

2. Need for clarity on legal framework. Across the region, there is a lack of clarity on the legal aspects of risk governance between the service provider and HCPs (e.g., for teleconsultation), hindering new collaborations. To manage India's evolving patient data governance regulation, Abbott worked closely with the Indian Council of Medical Research

and Central Drugs Standard Control Organisation¹⁸ to launch COVID-19 self-testing in India. However, in this instance, the impetus for collaboration was a matter of urgent national importance: to enable COVID-19 self-testing by developing companion reporting for disease surveillance and built-in artificial intelligence (AI) functionality for automated test result interpretation.

3. Need for better collaboration between public and private sector. There is room for APAC governments to further engage and collaborate with the private sector to

support care delivery, care innovation and best practices sharing. The greater use of such PPP would permit governments, payors and healthcare institutions to tap medtech resources in developing platforms for health service innovations that complement public sector efforts to address gaps in patients' access to treatment. In Singapore, for example, Fresenius and the National Kidney Foundation cooperate to manage capacity issues in the public sector and the overflow of CKD patients at dialysis centers.¹⁹

Case study: LivaNova's Connect patient data management system²⁰

Across APAC there is growing interest in improved connectivity between patient data management systems and hospital electronic medical record (EMR) systems, capturing the post-op data needed to achieve better patient outcomes. Patient data management systems are already present in most of mature Asia-Pacific. In countries like Singapore and Japan, the use of health data analytics is well established. In Australia, 95% of bypass surgeries entail the use of a patient data management system. In such mature markets, the creation of central registries (e.g., the Australian and New Zealand Collaborative Perfusion Registry and the Japan Adult Cardiovascular Surgery Database) is the trend. Comprehensive surgery data from hospitals provide a vital benchmarking resource for perfusionists. However, less-affluent APAC markets like the Philippines and Indonesia still rely on manual data recording by the perfusionist, and wide variances in the sophistication of their hospitals' EMR systems is another challenge.

Value: LivaNova's Connect perfusion charting system provides real-time and retrospective calculations and tools, assisting perfusionists with data management during and after cardiopulmonary bypass. The Connect system collects surgery data across various parameters (Hb level, O₂ saturation, arterial pressure, blood temp, etc.), minimizing transcription errors, bias and all the other drawbacks associated with manual operations.

The perfusionist has access to all perfusion data on one screen, allowing more time to concentrate on the patient and circuit. All data is exported back to the hospital's internal EMR system and manager database where the clinician may consult case-by-case statistical analysis and export or print EMRs. LivaNova's innovative and intuitive perfusion data management system delivers a simplification of the clinical data workflow, improved data integrity, enhanced legibility and a reduction in manual processes. Clinical benefits include fewer transcription errors and less bias,²¹ fewer manual entry inefficiencies, easier analysis and observed reduction in acute kidney injury.

Barriers: Across the region, policymakers have very limited awareness of the value of using patient data management systems in clinical practice, and few countries have provided funding to reimburse the clinicians' time to use such data to optimize their treatment practice and maximize patient outcomes. Taking Australia as an example, the Connect solution is categorized as hospital capex, and the use of data from it is not billable, not to mention reimbursable.

Strategies to overcome barriers: Medtechs with such patient data management solutions should work together to advocate with policymakers on the necessity of making such services billable to hospitals and reimbursing for such services as a technical fee to incentivize clinicians to use such innovative solutions to facilitate their clinical practice and optimize patient treatment outcome.

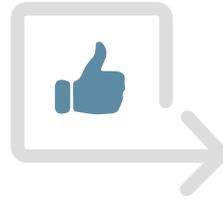
Clinical operations and analytics services

Figure 6
Clinical operations and analytics services



Outcome monitoring

- **Patient data tracking and benchmarking** (e.g., ChroniSense Medical's wearable medical-grade devices to monitor radial artery vital signs to manage coronary heart disease)
- **Monitoring of readmission rates** (e.g., Novartis partnership with Biofourmis to monitor heart failure to reduce hospital readmissions)



Clinical decision support

- **Clinical diagnostic tools** (e.g., Zebra Medical Vision AI-enabled assistant to analyze CT scans or X-rays and suggest clinical findings)
- **Discharge decision tools** (RightCare Solutions' Discharge Decision Support System to aid clinicians' discharge/referral decisions)



Operational efficiency

- **Workflow optimization** (e.g., Abbott AegisPOC connecting POC devices located in the hospital or community with the laboratory)
- **Resource management** (e.g., Quake Global QiAM asset tracking management to locate, track and manage hospital's resources, resulting in data to identify operational deficiencies)

Myriad new clinical operations and analytics services are improving efficiency and workflows, leveraging patient data tracking, and supplying practical diagnostic and decision-support tools. The three categories of clinical operations and analytics services (see Figure 6) are outcome monitoring, clinical decision support and operational efficiency.

However, deployment of innovative clinical operations and analytics services at scale has been slowed down by (1) limited awareness and utilization of generated clinical data, (2) limited financial incentives for HCP adoption and (3) stringent or ambiguous data privacy regulations.

- 1. Better utilization of clinical data.** Among healthcare providers and policymakers, there is only narrow awareness and use of medtech-generated clinical data to support clinical decision making and improve the patient experience. This is despite medtech's continuous efforts to educate providers and policymakers, and contribute to electronic health records (EHRs) data registries in a way that supports physicians in clinical decision making and the provision of care. Breakthrough collaborations are possible, however. For example, Baxter linked its ShareSource connectivity platform data with ANZDATA to examine treatment parameters of patients on automated peritoneal dialysis (APD) and provide advice to patients to improve the PD experience.^{22, 23}
- 2. Need for better financial incentives.** In most APAC countries, financial incentives to motivate healthcare

providers to adopt patient monitoring systems that track and evaluate treatment outcomes in support of clinical decision making are either inadequate or absent. Although not a direct incentive, securing reimbursement could be the first step to drive physician use of the service by overcoming affordability considerations. Abbott's continuous glucose monitoring system (FreeStyle Libre) demonstrated lasting socioeconomic and clinical value in Japan, which in turn allowed Abbott to secure national reimbursement for the system.²⁴ Alternatively, demonstration of a reduction in operational cost for healthcare providers could further drive adoption. Hillrom highlighted a reduction in HCP costs incurred to a third of conventional retinal imaging with the use of its RetinaVue solutions.

- 3. Stringent patient data privacy regulations.** Stringent data privacy and sovereignty regulations and guidelines often result in siloed data collection in hospitals and at a larger scale precludes cross-border sharing of patient data, thus hindering the development of cutting-edge medtech analytics platforms. Abbott's AegisPOC point-of-care management solution attempts to overcome this hurdle in provider settings utilizing a platform connecting point-of-care (POC) devices in hospitals/laboratories (elaborated further in case study [below](#)). The service potential for the use of real-world data (RWD, the raw intelligence from existing healthcare settings such as EMRs, observational studies, patient registries, patient-reported data, mobile devices, and claims and

billing data) and real-world evidence (RWE, generated from the application of analytic techniques to RWD) is drawing worldwide attention. One such example of RWE is Fresenius demonstrating a 15% reduction in patient dropout following the adoption of its EuCliD clinic information system.²⁵ The

promise of RWD/RWE to change clinical practice and deliver better patient outcomes is transformational, especially in light of the U.S. Food and Drug Administration's push for RWD/RWE use in post-marketing authorization to shape regulatory and reimbursement decisions of treatment options.²⁶

Case study: Abbott AegisPOC management solutions²⁷

Lacking connectivity and coordination and wanting to push POC systems to the primary care level, a private laboratory in New Zealand started rolling out AegisPOC just before the start of the pandemic in 2019.

Value: Abbott's AegisPOC point-of-care management solution is a web-based, open platform that connects the point-of-care devices in the hospital or clinic with the laboratory. The vendor-agnostic and cloud-based management system gathers data from multiple devices and presents them in a useable format. Launched in New Zealand, a frequent test bed for new technology, the system helps community and hospital services store and analyze the growing volume of POC data routinely collected from patients. An enabler of the increasing sophistication of POC technology, the AegisPOC system works across GP clinics, emergency departments and hospital wards.

With AegisPOC, the lab is the hub of the entire system. It integrates POC devices with laboratory information systems,

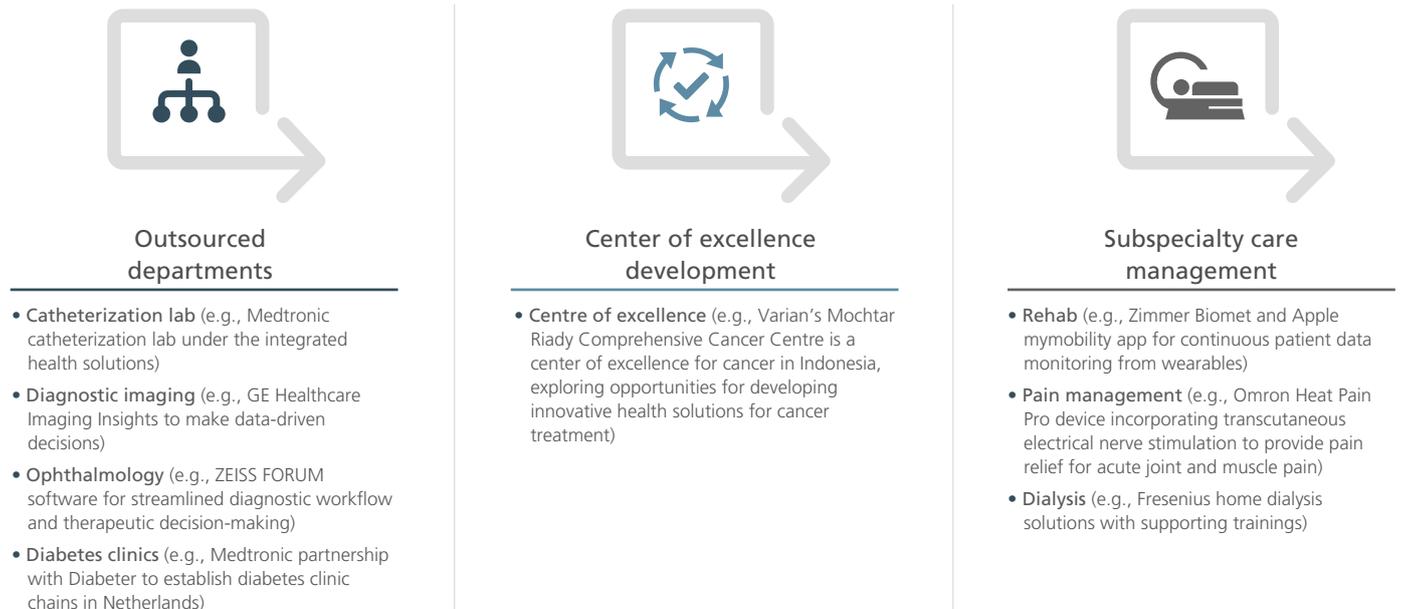
health information systems, EMRs, quality management, user management and other systems, completely replacing the need for multiple proprietary middleware. In addition, data management is significantly improved as POC devices are brought together seamlessly. Digitally connected, data-driven rapid diagnostics anchored to a central reporting database have a positive effect on other aspects of public health management and offer the potential for better health outcomes.

Barriers: The COVID-19 pandemic has proven beyond all doubt the value of rapid diagnostic tools. However, barriers to associated services persist. One such challenge is the siloed nature of POC data collection, a practice that hampers trend analysis and limits hotspot identification and contact tracing.

Strategies to overcome barriers: Abbott works closely with the client to implement a scalable connectivity solution that can be used by hospital networks and community clinics, independent of IT infrastructure. Southern Community Labs (covering the South Island of New Zealand) went from having 10 devices with the district health board to 53.

Direct-to-patient clinical services

Figure 7
Direct-to-patient clinical services



Traditionally, direct-to-patient clinical services are delivered by healthcare providers. The emergence of direct-to-patient clinical services from medtechs has been led by unmet needs and underserved markets, such as in chronic disease management for renal disease and diabetes, or pain management and rehabilitation. Medtechs contribute directly to the healthcare service capacity here, thereby transferring patient load from the existing healthcare system and expanding access to healthcare for patients, especially in offering cost-effective options for long-term chronic care, as well as addressing gaps for highly specialized treatments through centers of excellence.

Direct-to-patient clinical services include both fully owned medtech care delivery sites or partnerships with healthcare operators to provide clinical services to patients directly. These include three categories of services, namely outsourced department, center of excellence development and subspecialty care management (see Figure 7).

The main barriers to direct-to-patient clinical services are (1) need to leverage public-private partnerships and (2) perceived competition with local healthcare systems and domestic care providers.

1. Better leverage of public-private partnerships. Many APAC government policymakers are wary of overdependence on third parties for essential care delivery. This, in addition to medtech companies' lack of experience with strategic partnerships for care delivery, tends to deter governments from pursuing PPPs in direct-to-patient clinical services. However, where the need is acute and/or urgent, there is potential for greater flexibility. Fresenius successfully collaborated with a China provincial government to develop guidelines for stand-alone dialysis centers that reduced the burden on overstretched publicly owned and operated facilities (elaborated further in case study [below](#)).

2. Perceived competition. Healthcare providers fret about the possible cannibalization of existing business where medtech direct-to-patient services overlap with existing service offerings. A strategic agreement clearly stating risk sharing and mutual benefits is essential to mitigating these concerns. Cancer Treatment Services International, a Varian company, signed a strategic partnership with AC Health to operate the first cancer specialty hospital in the Philippines, providing high-quality, affordable treatment options.²⁸

Case study: Fresenius Medical Care's kidney care services in China

Only a small proportion of kidney patients in China can be treated at present, fewer than half of those with CKD.²⁹ China's government recognized the need for greater access to affordable services when it announced a national policy shift at the end of 2016 to allow private investment in stand-alone dialysis centers. Fresenius Medical Care (FMC) has since developed and executed its plans to offer dialysis services to patients, communities and provinces. It now operates six renal hospitals and 25 stand-alone dialysis centers in China.

Value: In addition to the inherent value of enhanced patient access to the best possible dialysis treatment, FMC's clinics and hospitals are essential components of local healthcare ecosystems. However, FMC's China market entry success has yet to include some of its most advanced healthcare technology services. FMC's EuCliD clinical database system is at the forefront of dialysis machine learning and the use of AI to accelerate and improve medical decisions.

EuCliD, FMC's proprietary clinical information system, captures patient clinical data during dialysis to continuously monitor the quality of care delivered, while also using patients' metadata to perform predictive medicine. In many markets where EuCliD is part of the treatment protocol, an integrated Doctor App collects and evaluates defined indicators to help the care team improve treatment. Doctors using the app are able to see real-time patient treatment data and respond remotely, directly adjusting dosage levels to be administered by the on-site nurse. Especially in times of a pandemic, this decreases physical interaction to keep vulnerable patients safe while still maintaining quality treatment.

AI modules can be added to the EuCliD interface to predict certain outcomes or needs for interventions such as hospitalization due to the likelihood of a change in the patient's condition and give doctors' recommendations accordingly. The Anaemia Control Module is an example of drug administration for dialysis patients. Usually, standard blood clotting drugs are administered during dialysis; AI is used as a decision support tool to recommend a lower or higher dosage based on the patient's condition, ultimately providing personalized drug administration for each patient.

Barriers: FMC is working within China's patient data privacy regulations to pilot the EuCliD system in its clinic network. All servers containing patient data must be located inside mainland China. Currently, Hong Kong, where FMC's main servers are located, is not deemed acceptable by the mainland authorities. To support the EuCliD pilot program, FMC has therefore installed servers in China and complies with all relevant laws and privacy regulations, such as anonymizing patient clinical data. With patient privacy in mind, guidelines still have to be developed that include safe data sharing between mainland China and Hong Kong. However, with the rise of digitalization and digitized models of care, strict regulation on the handling and sharing of bio-information delays the introduction of cutting-edge data technology to the market — often to the detriment of China's dialysis patients.

Despite the market opening for healthcare services in China, licensing is not easy, as the government remains cautious. Bureaucratic hurdles include the various business and medical licenses as well as securing reimbursement from the Basic Medical Insurance programs covering dialysis patients. Most approvals must occur sequentially rather than concurrently, increasing costs and time to market. Current regulations require private medical providers to invest heavily in human resources and physical assets before applying for licenses — a burden of upfront costs long before any revenue can be realized.

The biggest bottleneck relates to medical insurance, which continues to develop at a slow pace. Depending on the city, regulations require FMC to have at least three months of patient data before getting insurance coverage. In order to achieve that, services providers must find ways to generate and collect data while offering the services free of charge. In total, the process can take anywhere from three months to three years. Patients could choose to pay themselves, but most cannot afford to do so and have the ability to receive care on a reimbursed basis at publicly operated institutions, where available.

Medical insurance is critical for dialysis centers. Depending on the province, government medical insurance covers 80% to 98% of treatment costs. Some city governments are starting to encourage dialysis centers and private hospitals to adopt a zero markup model for medication in line with the practice at public hospitals, further limiting the income streams available

to private operators to fund daily operations. This may also have an impact on the introduction of innovative products in the long term.

Medical literacy can also be an impediment. In China, dialysis procedures are formally referred to as hemodialysis, which is just one type of dialysis that can be provided. Furthermore, from a cultural perspective, reference to working with blood invokes fear of infection among local communities, which also have the power to reject the licensing of new dialysis centers.

Strategies to overcome barriers:

Serve the greatest need: Outside the major cities, there is less capacity for treatment and patients and communities with significant need. Obtaining the support of the local authorities is critical, especially in Tier 2/3 cities and with large- and midsize cities with populations of up to 15 million, like Kunming or Quanzhou.

A cooperative partnership with the government: FMC plays an important role in local dialysis ecosystems; more often than not, its stand-alone clinics are the first in the city, if not the province. Understandably, some local governments are unfamiliar with licensing procedures. FMC's dialysis centers in China were mostly greenfield investments and, as such, required extensive efforts to secure the necessary approvals, including the development of standard operating protocols

(SOPs). FMC collaborates closely with the municipal health authorities and relevant stakeholders in the care setting to provide as much support as possible.

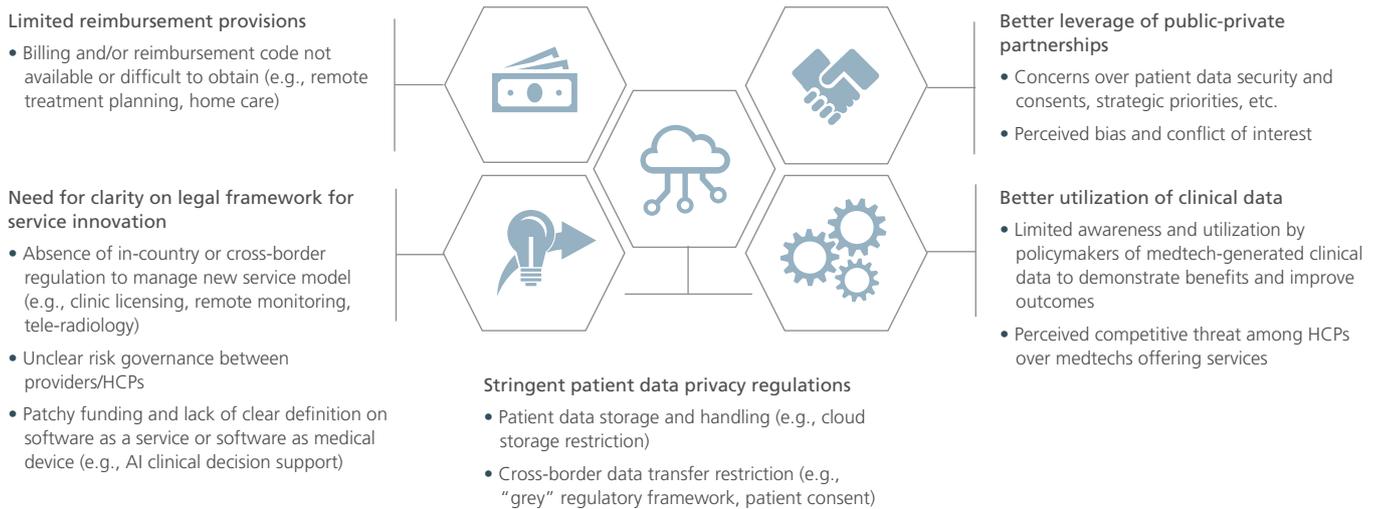
Local barrier avoidance: Decision-making and approvals are highly localized in China. Before approaching any new location, FMC enters into extensive preliminary discussions with local health insurance bureaus and local health departments to understand the current and near-future policy environment, city by city.

Demonstration effect: FMC hopes the authorities will start to give some weight to its track record as a major medical service provider with demonstrated value to healthcare systems and success stories across China's cities and provinces. It would be helpful if this could then be used as a reference in terms of licensing processes, clinical SOPs, performance criteria, etc. in other regions. Greater speed and agility in licensing subsequent projects would be beneficial for all stakeholders to provide adequate care to patients and communities in need.

Facing an array of impediments, from licensing issues to insurance regulations and medical illiteracy, FMC has nonetheless achieved remarkable success in China. However, despite its growing reputation in China, more stringent data privacy regulations may yet prevent FMC from deploying its more advanced healthcare services.

Key considerations for policymakers, institutional payors and providers

Figure 8
Overview of opportunities for improving health services landscape



Note: HCP — Healthcare professionals
Source: L.E.K. research and analysis

The medtech industry has excelled at producing cutting-edge medical devices, therapeutics and health technologies for decades. With growing recognition of unmet needs in specific patient groups, providers and populations, medtechs have stepped into the provision of services to maximize the efficiency, capacity and responsiveness of healthcare systems. Their health services offerings include: (a) clinical education services — upskilling of physicians and empowering patients, (b) care coordination — end-to-end care provision using digital technology, (c) clinical operation and analytics — clinical decision support using medtech data analytics, and (d) direct-to-patient clinical services — care delivery sites, fully owned or in partnership with healthcare providers.

However, medtech services, like other health services, still face numerous barriers, as discussed in the earlier sections. To this end, the opportunities for improving the health services landscape include reimbursement provisions, legal framework, data privacy, PPP and clinical data utilization as summarized in Figure 8. Unlocking these opportunities will require support and collaboration across stakeholders, including policymakers, institutional payors and healthcare providers, to deliver true patient-centric care and benefit the healthcare system.

Policymakers play a critical role in galvanizing change, setting the incentives for permanent shifts to more effective patient care

through the adoption of innovative services. Policymakers should proactively review policies, investments and protocols to facilitate equitable access to healthcare services. Key recommendations include:

- Establish open communication with industry leaders (e.g., through forums, coalitions) to mitigate concerns over patient data privacy, understand the trade-offs with digital innovation and ultimately establish transparent guidelines and a conducive regulatory framework.
- Work toward developing policies to overcome unnecessary barriers to data sharing and patient privacy. The healthcare data analytics revolution using real-time and historical industry data will reveal new paths to patient care quality, clinical insights and diagnosis.
- Ensure the care delivery regulatory guidelines are suitable for innovative services and providers of services, including provisions for revisions/renewal of regulatory regimes to ensure sustained applicability. One priority should be revisiting existing regulations of care-at-a-distance to enable greater access and flexibility through connectivity solutions.
- Support service innovation through sponsorships (e.g., co-funding, grants) and the piloting of breakthrough healthcare solutions (e.g., regulatory sandboxes) involving PPP.

-
- Consider the social benefits of better access and quality of care delivered in novel and innovative ways by services suppliers (e.g., improved patient convenience and productivity from reduced traveling needs to seek treatment in acute care settings) when developing relevant policies and guidelines.

Institutional payors could support greater access to and the uptake of new health services that have been shown to have the most significant impact on patients' lives and well-being. Key recommendations for payors include:

- Ensure greater flexibility in financing innovative services. Payors should not be constrained by existing funding policies that provide reimbursement largely to acute care institutions.
- Encourage healthcare providers to innovate care delivery models at a greater value by actively considering options such as outsourcing/collaborations with trusted partners. Payor involvement, such as creation of reimbursement code or financing mechanism, is valuable to drive access, utilization and visibility. Further, this would allow for the expansion of overall capacity and/or services offered, producing a virtuous cycle of scale economies.
- Provide integrated reimbursement opportunities over full episode of care to enable care transition across settings — such as using step-down health services by medtech enterprises to free up capacity at acute care institutions or investment in early intervention to reduce the overall cost of an episode of care.

- Reconsider Health Economics and Outcomes Research (HEOR) requirements for the medtech service proposition, where applicable. As appropriate, facilitate the use of alternative credible information sources — such as peer-reviewed articles — for assessment. Medtech services only deployed on a small or pilot scale initially (e.g., AI medical imaging, robotic surgery) may not warrant an extensive HEOR for payor approval.

HCPs and healthcare providers should view medtech health services as complementary catalysts for improved patient access, outcomes and more cost-effective care. Key recommendations for HCPs and their healthcare institutions include:

- Work collaboratively with medtechs in the form of co-development or risk-sharing agreements to innovate care delivery models. The goal is to expand the incumbent reach in the community through greater patient access to innovative healthcare services.
- Revisit the financial control framework such as shifting from fixed, annual budgeting to multiyear opex budgeting to enable procurement and adoption of new health services from medtech.
- Facilitate the involvement of industry stakeholders to contribute to the drafting of clinical standards and guidelines, strengthening the process through the introduction of global expertise and best practices.
- Recognize the role of medtechs in facilitating more efficient care and adding value to care delivery services offered to patients.

Methodology

The analysis on health services paper is based on extensive secondary research from several sources, including medtech corporate websites, published articles and reports, and primary

research through interviews with medtech industry executives, healthcare providers, payors and academicians.

Glossary

APD	Automated peritoneal dialysis
CKD	Chronic kidney disease
CTSI	Cancer Treatment Services International
DRE	Drug-resistant epilepsy
EHR	Electronic health records
EMR	Electronic medical records
Hb	Hemoglobin
HCPs	Healthcare professionals
HEOR	Health economics and outcomes research
HIS	Health information systems
ICMR	Indian Council of Medical Research
ICT	Information and communication technology
IV	Intravenous
LIS	Laboratory information systems
NKF	National Kidney Foundation
POC	Point-of-care
PPP	Public-private partnerships
RWD	Real-world data
RWE	Real-world evidence
VAM	Vascular access management

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Category	Company	Country	Case study
Clinical education services	Baxter	Japan	Secured reimbursement for CKD shared decision-making in Japan
	BD	APAC	Established Vascular Access Management service in Australia
	BD	Global	Launched mobile apps for patient education on insulin injection techniques
	Fresenius	Korea	Established renal care training hub with the support of Korean Society of Nephrology
Care coordination services	Abbott	India	Worked with Indian regulatory authorities to launch COVID-19 self-testing kit
	Baxter	Australia	Established ShareSource connection with ANZ data registry
	Baxter	Korea	Secured temporary reimbursement of remote patient monitoring software, Sharesource, during COVID-19 pandemic
	Fresenius	Singapore	Collaborated with National Kidney Foundation to resolve public sector dialysis capacity issues
	LivaNova	APAC	Developed Connect patient data management system to facilitate surgeon education
	ResMed	India	Set up AirView cloud-based patient management system
Clinical operations and analytics services	Abbott	India	Launched COVID-19 antigen test kit together with NAVICA app for data surveillance
	Abbott	New Zealand	Set up Abbott AegisPOC Management Solutions to connect POC devices
	Abbott	Japan	Demonstrated clinical and socioeconomic value to obtain reimbursement for FreeStyle Libre
	Fresenius	U.S.	Presented RWE for EuCLiD information system
	Hillrom	Global	Developed RetinaVue solutions to support retina imaging and clinical decision-making
	LivaNova	APAC	Developed vagus nerve stimulator implants combined with clinical support services
	Medtronic	U.S.	Developed CareLink, an implanted heart monitoring system
Direct-to-patient clinical services	Abbott	U.S.	Set up NeuroSphere virtual clinics for chronic pain management
	Fresenius	China	Collaborated with a China provincial government to develop guidelines for standalone dialysis centers
	Varian	Philippines	Signed strategic partnership with AC Health to set up cancer specialty hospital

About APACMed and L.E.K. Consulting

About APACMed

We provide a unifying voice for the medical devices and in-vitro diagnostics industry in Asia Pacific

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 Asia Pacific. Our 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.

Promoting innovation and impacting policy that advances healthcare access for patients

ACCESS: Improve access to high-quality healthcare for patients.

INNOVATION: Support innovative new technologies and startups that improve the quality of care and healthcare outcomes.

HARMONIZATION: Aligned with international best practices promoting speed to access via common regulatory standards.

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