



Health Policy
White Paper

Charting a Path for Sustainable Healthcare in Japan

The American Chamber of Commerce in Japan

Published by:
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Introduction

Japan faces a very modern problem: its success in delivering universal health coverage and fostering longer life expectancy has led to demographic and social changes that give rise to a new set of interconnected healthcare challenges. The COVID-19 pandemic has exacerbated many of these challenges, bringing the importance of investment in health to the forefront of policy issues. The response to the ongoing pandemic has placed additional strain on the healthcare system and stretched national finances. As the Japanese Government moves to reform its healthcare system to address these challenges, we encourage Japan to develop new policy approaches that promote innovation in all areas of the healthcare system so that Japan can continue to make advances in healthy life expectancy, improve productivity and move to the next phase of economic growth, while maintaining Japanese patients' access to the most cutting edge medicines, technologies and treatments as well as the security and stability of Japanese health and social care provision.

At the root of these challenges is the dramatic aging of Japanese society and its low birth rate. Nearly a third of Japanese people are aged 65 and over, and that percentage is expected to rise to 45% by 2050. Aging populations create pressing needs in nursing care and chronic disease care in areas including diabetes, dementia, heart disease and cancer. As the population ages, health is increasingly in the financial spotlight: national expenditures on healthcare hit a record high in FY2019, reaching ¥44.4 trillion, up ¥994.6 billion from the year prior (¥351,800 per capita).

As the Japanese Government has recognized, adapting to this situation requires a variety of policy approaches, including improving the fiscal sustainability of the social security system and fostering a more dynamic society with higher productivity and more women and seniors in the workforce. Against this backdrop, it is clear that health should be viewed as an investment: improving the health of Japanese people will be critical to reducing cost, lowering the incidence of preventable diseases and ensuring that more people can lead active, productive lives well into their senior years.

More than most nations, Japan is capable of meeting these challenges: healthy life expectancy in Japan—the age until which people can live without sustained medical or nursing care assistance—is about 71 and 74 years on average for men and women, respectively. With the right policies and approach to healthcare, Japan can continue to improve the health of its citizens and create a blueprint that aging societies across the world can follow.

The aim of this White paper is to introduce evidence-based global best practices that can assist the Japanese Government in the development and implementation of relevant policies. We have charted this path to sustainable health care across four key “actions.”

01 Invest in Prevention, Early Detection and Treatment

In recent years, the Japanese Government (hereafter the Government) has shifted its focus from simply caring for disease to applying the practices of prevention, early detection, and earlier aggressive treatment to reduce overall health care expenditures and sustain the productivity of its citizens. While much progress has been made, much more can still be done. As such, the ACCJ has outlined a wide range of evidence-based policy recommendations to support investments in prevention, early detection, and early treatment across several themes:

- Healthy Living & Well-being
- Communicable Diseases
- Non-Communicable Diseases
- Women's Health
- Childhood Medical Care
- Mental Health

In addition, from a more comprehensive perspective, we put forward a set of recommendations to accelerate these efforts even further:

- Implement a holistic approach to national-level preventive actions
- Accelerate innovative approaches to enhancing prevention, early detection and early treatment
- Empower and educate citizens to take control of their health

02 Maximize the Quality and Efficiency of Health Care Delivery through New Advancements in Digital and Data Innovation

The Government has recognized the need for better health care data management and has begun efforts to centralize data platforms and accelerate data-driven innovation programs, while at the same time, strengthening cybersecurity infrastructure to safeguard against external threats.

Despite these efforts, Japan trails other developed countries in the implementation of a comprehensive health care data platform. Much more should be done to incentivize the proper collection and utilization of healthcare-related data. Specifically, we suggest that the Government:

- Expand the reach of data collection beyond health care to achieve unique Japanese innovations
- Strengthen public-private partnership and citizen engagement to propel innovation
- Harmonize information sharing among public and private sectors to mitigate cybersecurity risk
- Ensure the usability of a future health care data platform

03 Foster an Appropriate Innovation Policy and Explore New Models of Reimbursement

In response to accelerated health care innovation in Japan, the Government launched its health care innovation initiative in 2014. Since then, the Government has pursued several broad initiatives for research and development (R&D) support and registration, authorization, commercialization and evaluation and reimbursement. Despite this progress, recent reforms to the pricing and reimbursement of innovative medical technologies threaten to undo the progress made in recent years.

With the clear purpose of delivering health care innovation to people in need as soon as and as safely as possible, we encourage the Government to increase its efforts to improve how it allocates physical, human and financial resources to maximize the potential for innovation. The Government should ensure that any new policies are fundamentally aligned with incentivizing innovation. We strongly urge the Government to:

- Reexamine the current reimbursement and pricing system to encourage and reward innovation
- Explore appropriate incentive packages to support the development of technologies of therapies needed by limited but underserved patient groups
- Provide end-to-end support and a robust partnership between academia and industry to accelerate innovation
- Discuss the future of fast-track registration and regulatory harmonization

04 Ensure the Financial Sustainability of Japan's Healthcare System

Japan's healthcare system is respected around the world for its quality of care and contribution to the long-life expectancy of Japanese people. However, the aging society and low birth rates are causing strain on a system that was designed mainly for controlling infectious and acute diseases within a different population structure.

Japan's national debt is more than double the size of its economy, the highest ratio among developed countries, and social security expenditures now account for approximately 33% of the national budget.

Improving the overall financial health of the system will be critical as the population ages, and as the size of the workforce continues to shrink. In addition to efforts to improve the efficiency of care delivery, this could also require steps such as increasing the healthcare budget in certain areas such as prevention, raising employer and employee contributions or increasing individual co-payments for healthcare costs, allowing mixed payment or providing incentives to purchase private-sector medical and nursing care insurance products. A long-term solution will likely require a combination of all these measures.

As the Government enters a critical period in terms of preparing the economy for the accelerated aging of Japanese society, now is the time to have an open, holistic and constructive debate that allows meaningful input from all key stakeholders. We strongly suggest moving this important discussion forward and encourage the Government to:

- Promote "Value-Based Healthcare" to increase efficiency
- Reevaluate the co-payment ratios of public insurance
- Secure necessary long-term financial resources to sustain Japan's universal health care system

Charting a Path to Sustainable Health Care – 4 Actions



01

Invest in Prevention, Early Detection and Treatment



02

Maximize the Quality and Efficiency of Health Care Delivery through New Advancements in Digital and Data Innovation



03

Foster an Appropriate Innovation Policy and Explore New Models of Reimbursement



04

Ensure the Financial Sustainability of Japan's Healthcare System

01 INVEST IN PREVENTION, EARLY DETECTION, AND TREATMENT SITUATION

While Japan maintains the longest life-expectancy among Organization for Economic Co-operation and Development (OECD) members, there is a 10-year gap between the average age of “life expectancy” and that of “healthy life expectancy.”¹ Extending an individual’s healthy life expectancy is critical to addressing Japan’s growing health care expenditures, and even more importantly, improving the quality of life and economic productivity of citizens. The Government recently published the “Healthy Life Expectancy Extension Plan,” announcing specific key success factors (KSFs) centered on three main themes: healthy life promotion; disease prevention and nursing care, frailty and dementia prevention.²

From a purely economic point of view, there are mixed perspectives on the ultimate return of prevention campaigns. That said, given the significant costs of treatment in later disease stages, programs that place a comprehensive focus on prevention, early detection, and aggressive treatment (in a medical condition’s early stage), are critical in managing total health care expenditures. For example, if diabetes develops to the most severe stage, patients require dialysis treatment. The annual cost of dialysis treatment is anywhere from ¥50,000 to ¥300,000 if it is detected early and more than ¥5 million in the later stages, representing an increase in cost of 20 to 100 times (Slide 1).³ Japan’s national spending on dialysis treatments rose to approximately ¥1.6 trillion in 2015.⁴ Reducing this cost through preventive, early detection, and aggressive treatments at the onset of diagnosis would make a significant impact in managing these specific health care expenditures.

Current Policy

The Government has begun to shift its focus from treatment to applying the practices of prevention, early detection and aggressive treatment to reduce overall health care expenditures and sustain the productivity of its citizens. The Government is employing a variety of initiatives, some of which are highlighted below.

Prevention

The Government has employed a number of measures to promote a healthy diet and lifestyle awareness and disease prevention. Moreover, the Government is seeking to expand the use and coverage of public vaccination programs.

Healthy Living

For the past two decades, the Government has promoted a healthy lifestyle policy branded “Health Japan 21,” which is currently in its second stage (2013 until 2023).⁵ Fifty-four Key Performance Indicators (KPIs) have been established in five categories, of which six KPIs are in the category of promoting healthy living conditions of individuals, including controlling daily salt intake, smoking prevention, increasing the average number of daily steps and adjusting the average workweek for employees to no more than 60 hours per week.⁶ Interim evaluations conducted in 2018, however, suggested that the Government’s measures have resulted in limited progress.

The Government has also established an award and recognition program for companies that promote positive health management initiatives for their employees. In doing so, the Government anticipates that such efforts at the company level will lead to healthier lifestyles for employees, which in turn, would prevent or delay the onset of severe medical illness, ultimately resulting in a longer healthy life expectancy.

In addition to national-level efforts, local governments are taking action. Recently, Hirosaki City (Aomori) established a Center of Healthy Aging Innovation (“Hirosaki COI”), where the area’s annual medical checkup data was utilized to establish new programs that support healthier behaviors in its citizens, leading to the co-development of healthy salt-free foods and a mobile health-check application.⁷

Public Vaccination

In recent years, many new vaccines have become available in Japan, and the number of diseases targeted by the National Immunization Program has increased. While the Government has made progress in narrowing the country's "vaccination gap," Japan still offers the fewest publicly-funded vaccinations in comparison to other developed countries.

In recent years, vaccinations against hepatitis B, *Haemophilus influenzae* type b (Hib), pneumococci, human papillomavirus (HPV), and Rota virus have been added to the National Immunization Program.^{8,9} The Government is also currently considering the possibility of adding vaccinations for the Mumps and Herpes Zoster viruses.¹⁰

While this demonstrates a positive step, not every disease that is targeted for the National Immunization Program achieves high vaccination uptake. As with the HPV vaccine (for cervical cancer), for which active recommendation was discontinued between June 2013 and April 2022, many vaccines fail to achieve adequate uptake, with some reaching less than a 1% uptake rate. In addition, there are several other vaccinations that have been publicly approved but have not been added to the list, as they have been under consideration by the Government for several years.

The timeline for evaluating new vaccinations for introduction and the criteria by which they are evaluated is not clear, which has made their public deployment significantly later and slower than in other developed countries. This has prompted concerned stakeholders to demand change.

Early Detection

The Government has made considerable improvements to increase the number of health checkups and screening for certain diseases to prompt early detection. In conjunction with the efforts to further promote annual health checkups for all citizens, the Government is also focused on increasing the rate of cancer screenings.

Cancer Screening

In 2019, the Government estimated that the annual loss of productivity caused by cancer in Japan exceeds ¥1.1 trillion. The Government recognizes the current cancer screening rate as alarmingly problematic—the cancer screening rate for breast cancer in Japan is only 30–40% compared to 70–80% in the United States and the United Kingdom. The Government aims to increase the cancer screening rate to over 50% over the next few years.¹¹ Local governments have taken various actions to raise awareness of the necessity for cancer screening. Many municipalities have conducted public awareness campaigns through direct mail programs, which has been the most effective method thus far.¹² Furthermore, the National Cancer Research Institute airs reminders for breast cancer screening on public outlets such as television, while in parallel, coordinated efforts are performed with municipalities to send follow-up reminders to those who have not yet been screened.¹³

Certain local governments have also been successful in improving the screening rate through innovative means. Hachioji City (Tokyo), for example, distributed notifications to its citizens highlighting the risk of colorectal cancers and thereby encouraging colorectal cancer screening by utilizing statistics obtained through the municipalities' medical record data.¹⁴

Early Treatment

The Government seeks to prevent further progression of diseases and other severe medical conditions by implementing early treatment. Due to these efforts, some local governments have been successful in promoting the prevention of certain nephropathies.

Diabetic Nephropathies Prevention

The Government has placed significant attention on preventing diabetic nephropathy, the leading cause of chronic renal failure. This is key in the Government's efforts to reduce health care expenditures due to the significantly high costs of dialysis treatment, where the main root cause is poorly controlled diabetes leading to diabetic nephropathy.

Certain local governments have taken innovative measures to prevent diabetic nephropathy while collaborating with private organizations. Kure City (Hiroshima) has witnessed significant improvements in diabetic nephropathy prevention by leveraging data from the public medical records of its local citizens. Such data and information were analyzed to identify individuals at risk. Follow-up and personal counseling were conducted to ensure that proper measures were taken to address their high-risk factors.¹⁵

Recommendations

The ACCJ has long believed that investment in health and well-being for the benefit of Japanese citizens would not only result in a higher quality of life but would also boost Japan's economic profile. As such, the ACCJ has outlined a wide range of evidence-based policy recommendations to support investments in prevention, early detection and early treatment. In addition to what is included here, the ACCJ has published recommendations spanning a range of health care topics, many of which are highlighted here (Slide 2-1, 2-2). In addition, from a more comprehensive perspective, the ACCJ strongly believes that the recommendations below will support Japan in achieving its goals in prevention, early detection, and treatment.

1. Implement a holistic approach to national-level preventive actions

While there are some successful cases in preventive health measures described above, they have remained strictly at the local level. Best practices should be adopted across Japan. Broader, national outreach would generate uniformity of disease prevention initiatives in the overall health care environment in Japan.

1a. Develop incentives for all local governments based on prevention and health promotion measures related to local needs

Incentivizing local governments is an effective way to replicate the successful results achieved in previously mentioned municipalities. As the Government has currently implemented some incentive programs for insurers, it should consider establishing similar arrangements including subsidies to motivate local governments to implement prevention and health promotion actions.

1b. Deliver initiatives in both conventional and digital platforms

The Government should direct its efforts to establish multi-sectoral task force teams to tackle its health care priorities. Digital platforms and electronic health records (EHRs) can be utilized to share current best practices in every region.

The National Initiative for Dementia led by the Danish Government provides a successful case study. In Denmark, both conventional and digital approaches were leveraged to execute this program on a national scale. The Government established and funded a multi-sectoral professional task force for educating nursing staff, who visit every prefecture and provide hands-on practical training. This program also launched an E-learning tool to effectively and efficiently dispatch this critical educational information nationwide.

2. Accelerate innovative approaches to enhancing prevention, early detection and early treatment

The Government has already demonstrated successful cases of innovative business ideas at the local level that enhance prevention, early detection and early treatment. The Government should continually update its multi-stakeholder approach to leverage new ideas and technologies and accelerate positive gains from health care reform.

2a. Social Impact Bonds (SIBs)

The SIB program is a leading example in applying innovative approaches to prevention, early detection, and treatment. SIBs, originating in the United Kingdom, are a contract with the public sector or governing authority, whereby proceeds are dedicated to the betterment of improved social services (Slide 3). SIBs serve as an important trigger for innovation in public services by providing the resources required to establish experimentation and new approaches to address existing problems. SIBs have been an ever-increasing global trend since 2013, and accordingly, the Government has gradually accelerated these initiatives in several municipalities, including Kobe City (Hyogo) and Hachioji City (Tokyo) since 2017.¹⁶ Kobe has been actively focused on preventing diabetic nephropathy and Hachioji has been actively focused on preventing colorectal cancer. Both cases have resulted in significant positive outcomes, exceeding initial expectations (Slide 4).¹⁷ The Government should expand and accelerate such programs on a national scale.

3. Empower and educate citizens to take control of their health

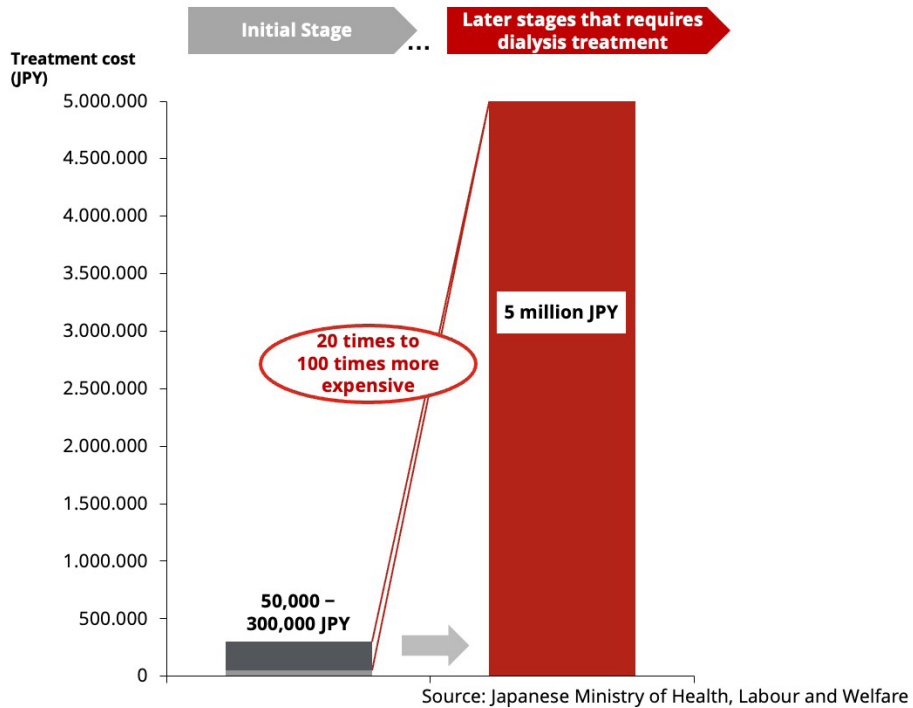
The Government should continue to emphasize the importance of healthy living and follow up on annual health checks of its citizens in new and innovative ways. Programs aimed at improving health literacy should be multi-channel, leveraging all available technological platforms. In addition, consumers should be provided access to their own healthcare data. Creating an environment where patients have access to their healthcare data makes it possible to create targeted incentives and health education programs to support individuals in taking control and developing healthier lifestyles.

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Slide 1

Treatment Cost in the Progression of Diabetes



Slide 2-1

**American Chamber of Commerce
Recommendation Summary by Healthcare Theme - 1**

Healthy Living & Wellbeing
From tobacco control to proper nutrition, self-medication, and vaccination, it is critical that people live healthy lifestyles and take the proper precautions to preserve their health well into the future.

Non-Communicable Diseases
The rising incidence of non-communicable diseases is a cause of increased economic burden and lower productivity across the world. With a rapidly aging society, it is critical Japan provides proper care for NCDs such as diabetes, cancer, and ocular health.

Women's Health
Amid efforts to foster greater female participation in the economy, improving the prevention and treatment of female-specific health conditions will deliver benefits not only to individual women, but also to families and society as a whole.

Slide 2-2

**American Chamber of Commerce
Recommendation Summary by Healthcare Theme - 2**

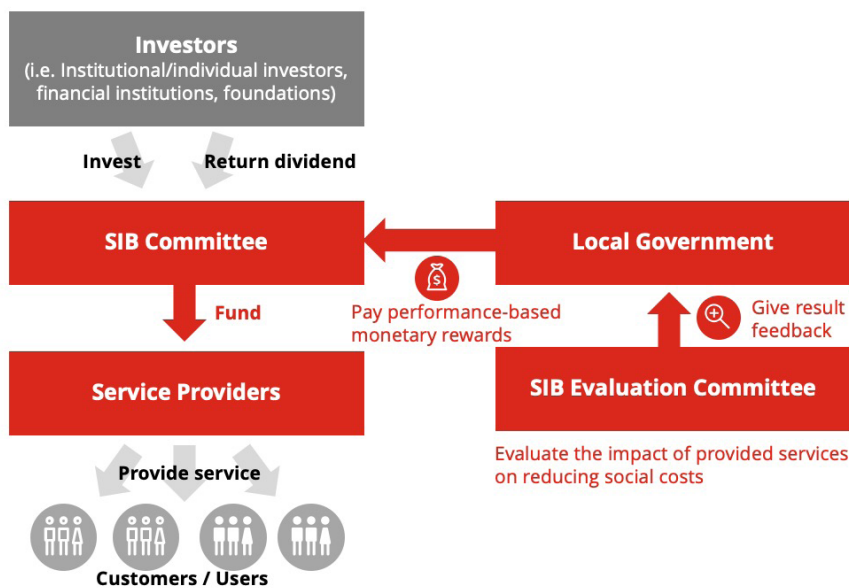
Communicable Diseases
Infectious diseases, even in developed countries, require adequate attention to ensure early detection, prevention of transmission, and appropriate treatment.

Childhood Medical Care
Facing a rapidly aging society, Japan's future is ever-more reliant on the health and well-being of its children. With significant regional gaps in access to care, it is important that Japan take action to ensure regional parity in healthcare access.

Mental Health
Emotional, psychological and social well-being is important at every stage of life, from childhood and adolescence through adulthood. Addressing the significant gaps in access to proper mental health care will help ensure that people can remain productive and lead fulfilling lives.

Slide 3

Social Impact Bond (SIB) System



Source: Japanese Ministry of Economy, Trade and Industry

Slide 4

Japan’s First SIB Projects in Kobe-City (Hyogo) and Hachioji-City (Tokyo)

	Kobe City (Hyogo)	Hachioji-City (Tokyo)
Running period	Jul 2017- Mar 2020	May 2017 – Aug 2019
Business Content	Prevention of Diabetes development and artificial dialysis through health guidance such as diet therapy	Early detection of colorectal cancer with customized screening recommendations by Artificial Intelligence, leveraging the past check-up tracking data
Target	Patients with diabetic nephropathy among members of Kobe National Health Insurance	Those who didn’t receive colorectal cancer screening in the previous year in Hachioji National Health Insurance
Intermediate Key Performance Indicator (KPI)	1. Completion rate of health guidance;80% 2. Life style improvement rate: 75%	1. Screening rate of colorectal cancer: 19% from 9% in 2015
Intermediate Result (as of Oct 2018)	<p>① 80% KPI, 100% Actual ② 75% KPI, 95% Actual</p>	<p>① 9% Before, 19% KPI, 29% Actual</p>

Source: Japanese Ministry of Economy Trade and Industry

02 MAXIMIZE THE QUALITY AND EFFICIENCY OF HEALTH CARE DELIVERY THROUGH NEW ADVANCEMENTS IN DIGITAL AND DATA INNOVATION

Current State

Japan is the world's most super-aged society. However, by promoting behavioral changes among its citizens, it has an opportunity to counter some of the negative impacts associated with an aging society. Ultimately, this will also support a more sustainable social security system.

Collecting, aggregating, and utilizing publicly available medical information is vital to the success of initiatives such as preventive medicine, the research and development of innovative medical technologies, and the improvement of care delivery. Moreover, as current medical practitioners continue to age and eventually retire from the profession, digitalization will become critical in providing high-quality, full care coverage to the Japanese population as well as better use of multi-disciplinary teams, including nurses and pharmacists.

Currently, Japan trails other developed countries in the implementation of a comprehensive health care data platform. According to an OECD survey, Japan's health care system ranks in the lower tiers for technical and operational readiness and data governance readiness related to the use of data for managing medical issues (Slide 1).¹ Among the data points demonstrating how far behind Japan lags in the field of digital health, the rate of EHR adoption is an outlier—hospital adoption remains particularly low at only 57%.² This is significantly lower than in the United States, where EHRs are deployed in 80%³ of medical facilities. There are successful examples of EHR deployment in countries such as Denmark, Sweden, and New Zealand, where adoption and use is approaching 100%.⁴ Furthermore, EHRs are maintained in various formats and information technology systems in institutions and regions across Japan, which hinders information sharing and connectivity. Other health-related data such as those collected during annual medical checkups are also not standardized or connected holistically.

Current Policy

In the 2022 "Honebuto Hoshin," the Government recognized the need for health care data management by centralizing data platforms and accelerating data-driven innovations programs, while at the same time, strengthening cybersecurity infrastructures to safeguard against external threats.

Initiation of Multiple National Health Care Databases in 2020

The Government has commenced the process to standardize and deploy multiple healthcare data platforms. The need for this initiative has been viewed as critical—the Government has increased spending upwards of ¥72 billion in 2019, a five-fold increase over the previous year.⁵

This initiative currently focuses on eight areas of service (Slide 2), which can be classified into four categories: 1) genome medicine and artificial intelligence research and development, 2) personal health records (PHRs), 3) platform for healthcare professionals, including EHRs, and 4) big data use and analysis.⁶ Initiatives to reform the current infrastructure to provide these services are also being explored, such as an online national personal identification system.⁷

However, according to the Japanese Ministry of Economy, Trade and Industry (METI), most of the data in PHRs are highly decentralized and vary in format among suppliers, which represents barriers to reform (Slide 3-1, 3-2).⁸

While efforts for reforming infrastructure are well-intentioned, there continue to be significant challenges in the transition to a national health care data platform, such as the lack of access to online records via secure internet links in some major teaching hospitals.

PHR Initiatives by Local Governments

Certain municipalities have already offered local PHR platforms to their citizens. Kanagawa Prefecture launched a regional PHR platform called "MY ME-BYO Carte," that was used by 1.2 million people (out of 9.1 million people) as of February 2019.⁹ This platform is connected to other health care application services (developed by private companies) and health insurance data platforms. Information compiled in this platform is also utilized as a means for future planning and strategizing for introducing healthy living promotions, child education support, and other local government initiatives.

Kobe City (Hyogo) also launched a PHR application called "MY CONDITION KOBE" in April 2019. The application tracks, measures, and monitors a variety of key health attributes while providing users tools for realizing the full potential of the application. Health attribute measures include, among other things, daily steps, sleep time, heart rate and logs to record daily nutrition, weight and certain other medical data. This application has other functions such as a point system to incentivize healthy living and an artificial intelligence counseling chat to provide personalized health care tips.

The Next Generation Medical Information Infrastructure Act (*Jisedai Iryo-Kiban Ho*)

The Government has made numerous attempts through legislative reforms to propel data-driven health care innovation to allow health care data to be analyzed and used by third parties.

The Government enacted the "*Jisedai Iryo-Kiban Ho*," (Next-Generation Medical Infrastructure Act) in May 2019 to allow medical big data to be edited to remove certain personally identifiable information before the data is pooled so that the data can be utilized to benefit research and development efforts for new drugs. Prior to enactment of this new law, individual health-related data such as illness records and medical checkup results were classified as "sensitive individual data" in the Law on the Protection of Personal Information. This limitation hindered the development of health and medical big data platforms.

The new law allows hospitals and clinics to provide patient data to authorized organizations that are accredited by the Government to receive and anonymize such data. Such organizations will be responsible for "cleansing" data, ensuring that all personal data are anonymized. This data will be made available to academic researchers and drug companies or government agencies for a fee. Hospitals and clinics that choose to provide such information would need to obtain patients' consent beforehand. Patients can opt-out if they do not wish to share their information (Slide 4).

While the enactment of this law garnered much attention in the hope that it would accelerate innovation and propel the data-driven business, only three third-party organizations have been certified by 2022.¹⁰ The government should promote this initiative so that active data utilization can accelerate innovation further.

Strengthened Personal Information Protection and Cybersecurity

The defense and mitigation against the risk of personal data breaches and cyber-attacks are critical for obtaining citizens' confidence and building trust by ensuring that information used in data-driven innovation systems will be protected.

The Government has strengthened its cybersecurity capabilities to protect data against external attacks by continuously updating and enforcing the personal information protection and cybersecurity laws and guidelines adapted for technological and social changes.

In regard to medical information, the Government has continuously amended its laws and guidelines for security management to align with legal-related revisions and the ever-evolving complexity and depth of cyber-attacks. The Government is currently updating the laws and guidelines to adapt to the increased complexity of information technology and changes related to medical information and the introduction of new national data platforms.¹¹

Recommendations

1. Expand the reach of data collection beyond health care to achieve unique Japanese innovations

The Government should consider expanding the reach of its data initiatives beyond health care. Daily behavior directly impacts health, and accordingly, the Government should consider the need to consolidate a wider range of characteristics and attributes to create a comprehensive data platform.

The Government should also consider expanding the scope of data collection to encompass all meaningful attributes while securing privacy and confidentiality for creating a national data set that is distinguishable from those of other countries. To enable personalized and in-depth data collection and analysis, the creation of personal health care IDs can be a possible solution to link medical data from clinics, hospitals, and other institutions. The introduction of such a measure may lessen the burden of health-related data collection from multiple sources. Moreover, this information, once anonymized, can be made available to the Government and various health organizations to plan national initiatives and to tackle complex matters within the Japanese health care system.

2. Strengthen public-private partnership and citizen engagement to propel innovation

The Government should consider strengthening the partnership with private organizations to drive the utilization of the data prepared in the public sector while engaging its citizens to ensure consensus and understanding of digital transformation.

The Singaporean Government is currently working with Fitbit, an American healthcare-related wearable device company, and has been supplying citizens with free fitness trackers since October 2019.¹² Singaporeans will be able to receive a health-tracking wearable device for free if they commit to paying \$10/month for one year to receive the company's premium coaching service. If users consent to share their data with Singapore's Health Promotion Board, health attributes will be collected and used in future healthcare-related initiatives.¹³ By introducing this partnership with Fitbit to benefit its citizens, the Singaporean Government aims to improve citizens' lifestyles through digital technology.

In Japan, the Ministry of Internal Affairs and Communications and the Ministry of Economy, Trade and Industry recently deployed the "Information Bank" platform to collect and utilize consented users' data and in return, provide benefits to them, including monetary rewards and coupons. The Government should consider incorporating similar initiatives specific to health care and develop ways to incentivize its citizens to share vital health care information for effective use.

3. Harmonize information sharing among public and private sectors to mitigate cybersecurity risk

In order to minimize the security risk while accelerating innovation, the Government needs careful analysis and prompt information sharing with public and private stakeholders.

Japan needs to establish a system for companies to respond swiftly to cyber incidents. For example, there are up to eight public institutes for the submission of security incidents, though it is not clear to companies where to send their security incident report,¹⁴ which makes it difficult for private companies to take immediate action.¹⁵

In the United States, the Department of Homeland Security automates the digitization of information sharing (automatic indicator sharing) by automatically selecting suitable information for each institution and implementing the counteractions.¹⁶ Governments should make continuous efforts to explore robust and agile information sharing to ensure the credibility and safety of the system.

4. Ensure the usability of a future health care data platform

Utilizing advanced analytics, modeling, and simulation to enhance decision support capabilities, cost-effective and sustainable solutions for both the prevention, diagnosis, and treatment of disease, as well

as the forecasting, real-time monitoring, coordination, and communications of public health threats are already possible and will grow in capabilities in the coming years as these leading-edge technologies take root. The following actions can assist citizens in Japan to benefit from innovative solutions with advanced technologies and data.

4a. Ensure data quality and platform accessibility to improve health care quality

The Government should constantly assess the quality of the data provided by the Government, hospitals, and academic institutions to ensure the accessibility of their data platforms.

Though top priorities are data anonymization and secure storage, a balanced approach to allow the consolidation of real world data/real world evidence and wider accessibility of the data will support efforts to propel innovation.

4b. Foster the awareness of utilizing health data platforms among citizens and medical practitioners

Given that academic researchers and industries are expected to utilize data, it is critical to ensure that medical and nursing care practitioners, payers, and citizens understand the value of leveraging health data for a better society.

The Netherlands demonstrates an insightful example in its national PHR initiative called the “MedMij” project. In order to ensure citizens’ understanding of the significance of its digital health and its soon-to-be PHR service, they have organized interactive events for citizens and opportunities to co-create the utilization guidelines with patient associations, engaging a variety of stakeholders in discussion well before the launch.¹⁷

Since the Government is currently focused on setting up an integrated platform utilizing Cloud Computing and Big Data, the Government should create an action plan to ensure the actual use of this data platform in line with common standards.

4c. Incentivize digital innovations to tackle challenges of medical/nursing care practitioners

Along with contributing to a higher quality of comprehensive medical/nursing care services and promotion of healthy living, both the Government and the providers themselves need to pay attention to resolving issues faced by healthcare providers.

Some of these issues include staffing problems of medical and nursing care and gradual deterioration of working conditions, including increasing and demanding working hours. While the Government is trying to improve the working environment within the medical industry by lowering the limits of overtime work, this problem cannot be solved without an in-depth review of how medical care is delivered, including the utilization of digital resources and innovation. The Government has been working with businesses and academia to set up the “AI Hospital System” to help with diagnosis and consultation tasks.¹⁸

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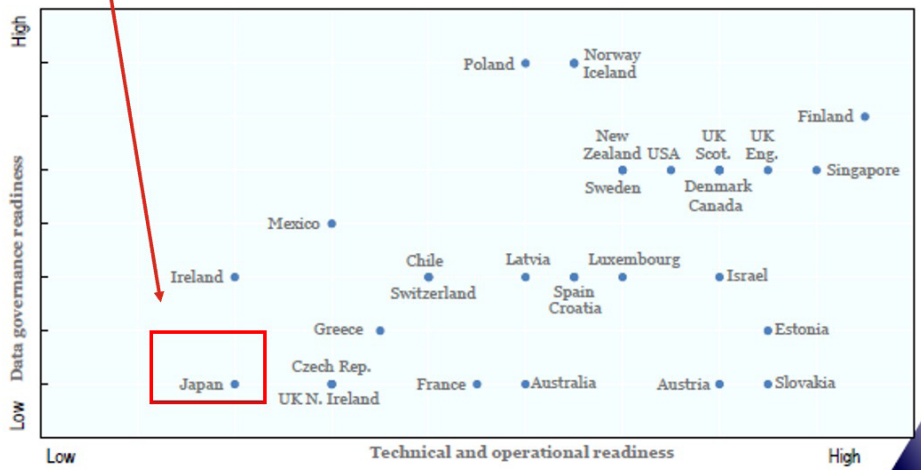
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Slide 1

Technical and Operational Readiness and Data Governance Readiness in OECD Countries

Japan's healthcare system ranks in the lower tiers for technical and operational readiness and data governance readiness



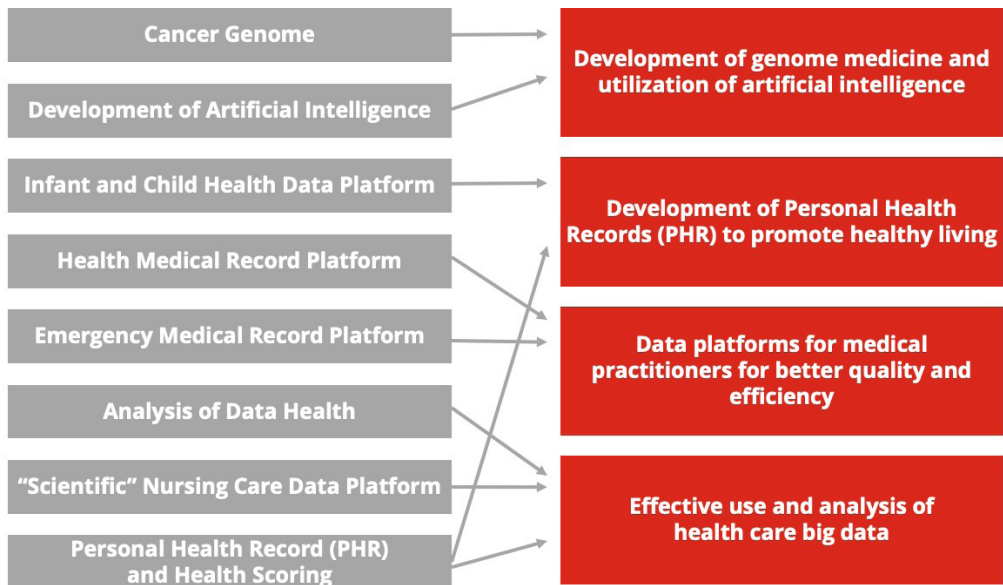
Source: OECD

Slide 2

Overview of the Government's National Healthcare Database Initiative

8 areas of focus (target launch: 2020)

4 Goals to be attained



Source: Japanese Ministry of Health, Labour and Welfare

Slide 3-1

Health Care Data Integration Status - 1
(as of May 2017)

	Type of data	Supplier	Existence	Digitalization	Standardization	Connectivity between suppliers	Connectivity to other types of data
Health	Health data of wearable and home devices	Private companies	×	○	×	×	×
	Health check up data of employees	Employer	△ <small>Check up ratio remains 81%</small>	○	△ <small>Standard format is not compulsory</small>	×	×
	Specific health checkup data	Insurers	△ <small>Check up ratio remains 48%</small>	○	○	×	△
Medicine	Health insurance claims	Medical institutions/ Insurers	○	○	○	×	△ <small>Connected to NDB</small>
	Diagnosis Procedure Combination (DPC)	Medical institutions	○	○	○	△ <small>Connected to DPC data base</small>	×
	Electronic Medical Record (EMR)		○	△	△ <small>Only in certain regions</small>	△	△

Source: Japanese Ministry of Economy, Trade and Industry

Slide 3-2

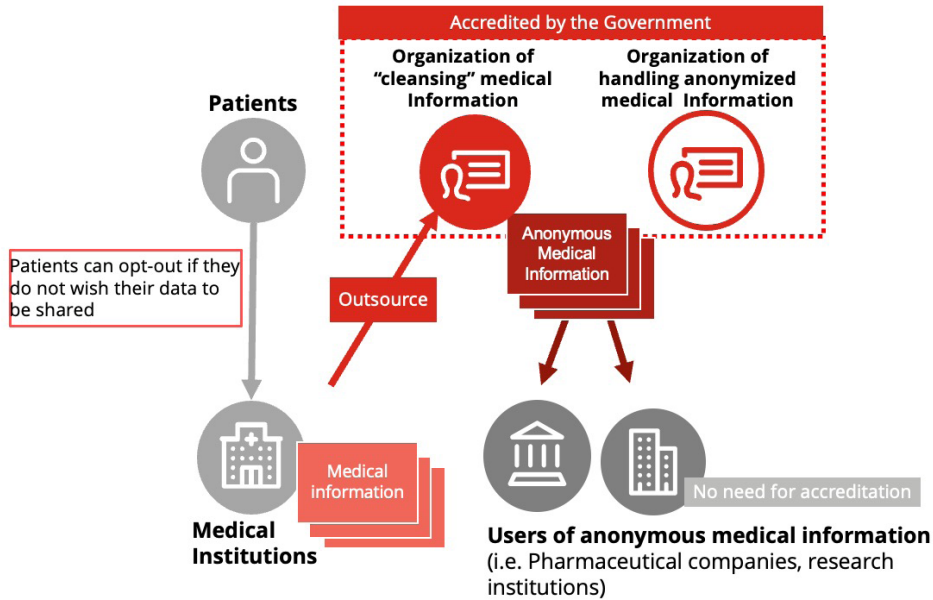
Health Care Data Integration Status - 2
(as of May 2017)

	Type of data	Supplier	Existence	Digitalization	Standardization	Connectivity between suppliers	Connectivity to other types of data
Medicine	Drug prescription data	Pharmacies / medical institutions	○	○	○	△	×
	Cancer registration data	Government (National Cancer Center)	○	○	△	-	×
	Pregnancy and childbirth data	Local governments	○	×	△	×	×
Nursing Care	Nursing care certification data	Government	○	△ <small>Utility rate remains very low</small>	○	-	△
	Nursing insurance premium record			○			
	Nursing care life log (i.e. diet, body temperature)	Nursing care institutions etc.	○	△	△ <small>Only in certain regions</small>	△	×

Source: Japanese Ministry of Economy, Trade and Industry

Slide 4

The Next Generation Medical Information Infrastructure Act (*Jisedai Iryo-kiban Ho*)



Source: Cabinet Office

Slide 5

American Chamber of Commerce Recommendation Summary for the Utilization of Digital and Data Health Innovations

Drug Development

Advancements in digital technologies are changing the way we develop drugs. Increasingly, modeling, simulation and other innovative technologies are being used to accelerate the drug discovery process. It is important that regulatory frameworks and healthcare systems evolve simultaneously.

Healthcare Delivery

From pandemic planning to providing efficient care, the application of innovative digital technologies can support healthcare systems to deliver even better care, more efficiently.

03 FOSTER AN APPROPRIATE INNOVATION POLICY AND EXPLORE NEW MODELS OF REIMBURSEMENT

Current State

Japan now faces formidable challenges in sustaining a leading position in the global pharmaceutical industry due to the ever-increasing cost of R&D and intensifying global competition.

Japan's efforts to promote a more competitive pharmaceutical industrial policy stand at odds with the Government's practice of utilizing drug price reductions to control social care spending. For example, between 2016 and 2018, more than 80% of the total savings for social security were made from price cuts on pharmaceuticals (Slide 1).¹ This tendency has remained a concern and a controversial point for industry stakeholders faced with the need to achieve greater returns on their investments to develop new drugs. Developing innovative medicines is a capital intensive undertaking. According to a recent study, developing a major new prescription drug is estimated to cost manufacturers, on average, \$1.4 billion and take an average of 14 years to obtain marketing approval.²

Highlighting the lack of a competitive industrial policy, Japan's biopharmaceutical companies only generated ¥1.8 trillion in market value—an amount 60 times smaller than the United States biopharmaceutical industry, which boasts a total value of ¥104 trillion.³

While the United States has become a fertile ground for academia-born venture companies in the biopharmaceutical industry, Japan has fallen behind. Approximately 80% of new drugs approved by the United States Food and Drug Administration are being developed by these nascent organizations.⁴ This is in contrast with the lack of such emerging growth companies in Japan, raising significant concerns for Japan's future innovative potential.

With these threats in mind, the Government has recognized the need to take appropriate action to stimulate innovation.

Current Policy

In response to the emergent need to accelerate health care innovation in Japan, the Government launched its health care innovation initiative in 2014, in conjunction with the foundation of related hub institutions, such as the Japan Agency for Medical Research and Development in 2015⁵ to assist with conducting the Government's health care research and development efforts. Since then, the Government has pursued various broad initiatives for R&D support and registration; authorization and commercialization; and evaluation and reimbursement cycles including:

R&D Support and Registration

Support for Venture and Emerging Growth Companies through Consultation

The Government has launched the "Medical Innovation Support Office" (MEDISO), which serves as an advisory committee specialized in health care venture support to startup companies.⁶ MEDISO supports these organizations to overcome challenges regarding funding and intellectual property and attempts to eliminate barriers to market entry to encourage innovation.

Accelerated Registration through Partial Revisions of the Pharmaceutical and Medical Device Act and the "Sakigake" program

The Government commenced its regulatory reforms with the partial revision of the Pharmaceutical Affairs Law in 2014 and enacted Pharmaceutical and Medical Device Act.⁷ This revision aimed to ensure safe and swift access to new drugs while providing adaptability to the unique market characteristics of medical devices. It also mandated the inclusion of package inserts and expanded the definition of medical devices

to adapt to the faster-paced market cycles.

Further revision of the Pharmaceutical and Medical Device Act is underway to clarify the status of innovative drugs, orphan drugs, and special-purpose drugs along with providing incentives to accelerate the introduction of such drugs for mainstream use.

The Government has encouraged the early evaluation and approval of critical new drugs with the “Sakigake” program and conditional early approval system once their efficacy at the early stage of clinical testing is confirmed. The pharmaceutical industry as a whole has applauded this development as it reduces the deployment lag for innovative products in Japan and accelerates commercialization.

Reimbursement and Evaluation

Pricing and reimbursement are strategically important to enhance the pace of innovation of the Japanese health care system as well as to ensure financial sustainability. This represents the most controversial topic related to health care legislation as there are multiple conflicts of interest among stakeholders. The Government has drastically increased the complexity of reimbursement and pricing through the reforms described in the following discussion, undermining the predictability and transparency of the market, hindering innovation.

Stricter Requirements for the Price Maintenance Premium System (PMP)

The PMP has been critical in promoting innovation in Japan and ensuring timely access to new and innovative drugs.

The Government implemented a new drug pricing package in 2018 to include several new pricing policies.⁸ In this reform, the government narrowed the number of products and companies eligible for PMP, cutting 30% of patented medicine out of the PMP scope. Recent data has shown the year-on-year increase in the number of clinical trials in Japan seen after the PMP has come to a halt and the number of clinical trials in Japan is now lower than in countries such as China and Korea. There is a high risk that the PMP criteria put in place in 2018 will not be effective in boosting innovation. The new product criteria required to obtain PMP are not science-based as they only focus on the speed and the order in which products are launched, which do not truly measure the “innovativeness” of such products.

Furthermore, requirements were established based on the product’s history of use in Japan, which appears to be inherently biased to favor large domestic companies. As a result of these factors, the Government’s commitment to fair and non-discriminatory policies has been called into question.

Increased Frequency of Price Revisions

Recently, the Government has revised prices at a more frequent pace, including the consumption tax increase in October 2019.

The Government determined that it would implement an annual price revision system to commence from 2021 for pharmaceutical products and is currently considering extending the system to also cover medical devices. The Government has also considered expanding the scope of target products subject to annual price revision.

Specific to medical devices, the Government recently reduced the gap between Foreign Average Price (FAP) and reimbursement prices in Japan. The Government is also attempting to reduce the number of functional categories to simplify the Medical Fee Schedule. Merging certain categories together will lower the reimbursement amount for high-cost categories, which usually represent the new, innovative product types.

The increased frequency and unpredictability of pricing revisions undermine certainty and predictability of economic metrics for pharmaceutical and medical device companies; which in turn, has a negative “knock-on” effect on innovation.

Launch of Value-based Healthcare with Health Technology Assessment (HTA)

With the emerging concept of “Value-Based Healthcare,”—a new health care delivery model in which medical services are paid based on patient health outcomes—Japan officially introduced the HTA system for pricing adjustments on pharmaceuticals and medical devices in 2019 after a trial phase in 2016.⁹ HTA is the scientific procedure of evaluating the return on investment in health delivery when determining the cost of premiums and health expenditures. While the HTA was established several years ago in other developed countries such as the United Kingdom, Germany, Canada, and Australia among others, Japan only recently adopted this initiative in recent years.

Specifically, the Japanese HTA is uniquely different as it only applies an incremental cost-effectiveness ratio, while other countries consider a broader range of factors in their assessments. Japanese HTA also sets a lower cost/quality-adjusted life year (QALY) threshold when compared to other countries (¥5 million per quality-adjusted year for general products). The validity and effectiveness of this threshold has been met with criticism from academia and industry, with many stakeholders arguing for the need to make significant improvements to the current scheme to better reward innovation and foster the further advancement of a value-based approach to evaluating new healthcare technologies and interventions.

Examination of the Mixed Billing System

The Government has explored the possibility of increasing the flexibility of its reimbursement system including mixed billing, which has required prudent discussion due to the high risk of increasing access gaps and aggravating the problem of public reimbursement manipulation by overcharging for medical services.

As of September 2021, the Government allows mixed billing for only two types of services: assessment treatments and selective treatments.¹⁰ The Government has also examined the possibility of expanding the scope of mixed billing by defining new medical services.

Recommendation

With the clear purpose of delivering health care innovation to people in need as soon and as safely as possible, the ACCJ encourages the Government to increase its efforts to prioritize meaningful healthcare interventions, evaluating how it allocates physical, human, and financial resources to maximize the potential of new innovations. The Government should ensure that every policy is fundamentally aligned with the goal of incentivizing innovation.

1. Reexamine the current reimbursement and pricing system to facilitate innovation

The Government has not aligned its reimbursement and pricing policies to promote innovation, but rather they undermine its potential. The ACCJ encourages the Government to reassess existing policies from the perspective of delivering the most effective and innovative medicines to patients in Japan.

1a. Enhance the HTA System to align with rewarding innovation (Slide 4)

The current HTA system should be reexamined to provide appropriate reward for innovation, as opposed to acting solely as a cost-containment measure. The current HTA system has been criticized for its inflexibility as it focuses only on incremental cost-effectiveness metrics.

Observations and results from examples outside of Japan have indicated that a more sophisticated HTA system should be established.

First, the cost-effectiveness ratio is only one of the multiple criteria used for an evaluation in many other countries. A level of flexibility is needed to capture and consider other factors and generate an appropriate incentive for the development of innovative products. For example, the Netherlands

continuously explores increasing the quality and transparency of its system by assessing other criteria such as the severity of target diseases, demand, efficacy, and social accountability of certain drugs.¹¹ Thresholds are also continuously evaluated and revised, when necessary, in accordance with the severity of target diseases.

In another example, to ensure continued access to innovative medicines, Germany conducts an HTA assessment of new drugs one year after the launch.¹² This differs from most markets where the assessment outcome is required prior to reimbursement. By assessing additional benefits versus existing alternative drugs one year after the launch, they can also utilize real-world data to inform the assessment.

Lastly, there are significant questions around the scientific validity of the cost-effectiveness thresholds in Japan, currently set at ¥5 million per QALY for general products. More research is necessary to address the validity of this threshold from an economic and health systems perspective.

1b. Reexamine the current pricing policies to incentivize Innovation

As explained, the Government's current reimbursement policy has been called into question for its excessive focus on cost containment and its discriminatory position against smaller and/or foreign-based companies, failing to become a true incentive for innovation.

For example, the repricing market expansion rule that was established decades ago to address significant market changes has created a negative impact on the development of new drugs. The rule mandates that prices for a medicine that exceed a certain marketplace threshold will be reduced, thus hampering efforts to introduce additional indications for existing therapies and other new, innovative products as therapeutic uses expand. This has a severe impact on the development of new drugs and disincentivizes the delivery of groundbreaking treatments to patients.

These disincentives are also seen in the medical technology sector, where more frequent price adjustments and continued debates on the future shape of the FAP rule and continued consolidation of functional categories has created a lack of market predictability, preventing manufacturers from delivering new products at a more accelerated pace.

We encourage the Government to consider reexamining these pricing systems to better incentivize innovation.

1c. Include organizations from industry into the decision-making process

As the Government developed its specific plans to execute the pricing reform initiative over the past few years, there have been fewer formal attempts by the decision-making bodies to seek input from industry stakeholders, which demonstrates a lack of transparency and inclusiveness. The Government is encouraged to seek the industry's perspective, providing meaningful opportunities to provide input and have an ongoing dialogue with decision-makers throughout the decision-making process.

1d. Reconsider the frequency and timeline of the announcement of pricing policy changes

The announcement of pricing policy reforms are often made only several months before implementation, which further increases unpredictability and makes it difficult for manufacturers to establish a clear business plans. The Government should reconsider the timeline to allow them ample time for stakeholder input in the rule-making process, while giving sufficient notice for major rule changes.

2. Explore appropriate incentive packages for each health care theme

The Government is encouraged to also consider special treatment for emerging global and national fields of health care development by incorporating the most appropriate push and pull incentives.

For example, antimicrobial resistance (AMR) is an emerging global issue that risks undermining the achievements of modern medicine. It is difficult to trigger innovation to address AMR due to acute market needs and uncertainty in profitability of products to treat AMR. To encourage the allocation of new resources to the development of new treatments, such as those used for AMR, the Government is encouraged to consider the adoption of incentives such as government stockpiling and procurement of these technologies and direct support for R&D by sponsors which would help to reduce the risk in such investments.

The Government is also encouraged to consider pull-incentives that reward successful innovations earlier in the product lifecycle. Since health care themes have unique concerns and risks that deter industry players from investing, the Government is encouraged to carefully observe and explore the most appropriate incentive schemes to propel innovation.

3. Provide end-to-end support and robust partnership between academia and industry to accelerate innovation

As noted above, the Government has taken multiple measures to trigger innovation through tangible measures including corporate tax adjustments for startups and emerging growth companies. However, there is no focus on end-to-end support, and in particular, support for the “exit” stage of the development process, such as commercialization upon final approval. Monetizing and strong partnerships between different professions and disciplines are key to creating an ecosystem to provide end-to-end support for innovation, for which the United States and the United Kingdom show positive examples (Slides 2, 3). As discussed previously, in the United Kingdom, the government has optimized its funding, practical testing, and partnership between academia and business.

The United States government has been successful in providing a special funding program for small and medium-sized enterprises along with a business education program to accelerate products and commercialization for drugs. Both the United States and the United Kingdom have built an ecosystem to ensure the optimal allocation of financial, physical and human resources to fuel innovation.

4. Discuss the future of fast-track registration and regulatory harmonization

While the Government’s continued efforts to reinforce fast-track registration and regulatory harmonization have been welcome, the Government’s near- and long-term plan for further change and evaluation remains opaque.

The Government is encouraged to continue discussing plans to further advance fast-track registration and harmonization in the discussions with industry bodies and to provide direction to the industry, which fosters increased predictability for ongoing and upcoming research and development.

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Slide 1

Social Security Budget over “Intensive Reform Period”

FY Budget	Saving Target	Saving by NHI price revision
2016	- 170 B yen	- 175 B yen
2017	- 140 B yen	- 20 B yen
2018	- 130 B yen	- 176 B yen



More than 80% of total savings generated from price cuts on pharmaceuticals

Source : Japanese Ministry of Health, Labour and Welfare

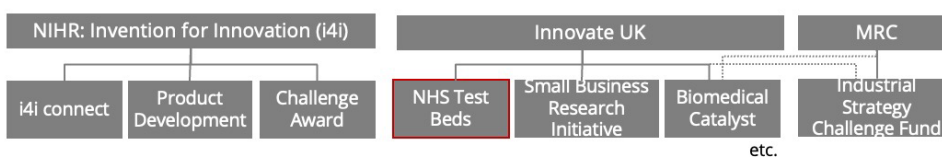
Slide 2

United Kingdom: End-to-End Innovation Support led by the United Kingdom Government



Optimal Funding through Various Specialized Programs

- A variety of healthcare-themed funding programs were offered by National Institute of Health Research (NIHR), Medical Research Council (MRC) and Innovate UK.



Enriched Practical Testing Opportunities

- National Health Service (NHS) Test Beds Program: Provide the practical clinical testing opportunities at NHS hospitals to accelerate commercialization

Hands-on Support from Diverse Experts

- Innovative UK: Committee of each program consists of clinical and business experts in each field, providing their hands-on support
- NIHR: A well-established evaluation system made by diverse experts enables funded programs to be improved based on “hands on” feedback

Source: UK NIHR, Innovate UK, MRC Website

Slide 3

United States: Funding and Education Programs for Healthcare Startups and Venture Companies in the National Institute of Health (NIH)

NIH

Small Business Research Initiative (SBRI) / Small Business Technology Transfer (SBTT)

Funding programs to allow small and medium-sized businesses to engage in federal research and development that has strong potential for commercialization, with the objective of translating promising technologies to the private sector and enabling life-saving innovations to reach consumer markets.

+

NIH Commercial Accelerator Program

- 9-month educational program to assist commercialization for healthcare companies funded by SBIR or SBTT, which enables them to establish market and customer relevance, build commercial relationships, and focus on revenue opportunities available to them
- Offers 3 types of commercialization programs based on the expertise and background of the enrolled companies

Commercialization Transition Track

Advanced Commercialization Track

Regulatory/Reimbursement Training Track

Source: National Institute of Health Website

Slide 4

Health Technology Assessment (HTA) System to be Aligned with Rewarding Innovations

Current HTA in Japan	Overseas Examples of HTA
Only apply a cost-effective model of quality-adjusted life years to the assessment	Apply multiple aspects including the severity of the target disease and social impacts (i.e. the Netherlands)
Assess the result from clinical test data	Assess the result from real world data post-launch (i.e. Germany)
Set the relatively low threshold of 5 million JPY for general products	<ul style="list-style-type: none"> • Set a high threshold of \$150,000 (i.e. the United States) • Adjust different thresholds in accordance with the severity of the target diseases (i.e. the Netherlands)

Source: PhRMA, "Newest Update of HTA in other foreign countries"

04 ENSURE THE FINANCIAL SUSTAINABILITY OF JAPAN'S HEALTHCARE SYSTEM

Current State

Japan, a nation with the highest life expectancy at birth among OECD members, maintains a high quality of life through an emphasis on a healthy lifestyle and access to leading quality medical care.¹ This is primarily attributable to a unique universal healthcare insurance system, *Kokumin Kaihoken*. In order for *Kokumin Kaihoken* to continue, the country's financial sustainability must be ensured. This notwithstanding, Japan has one of the highest levels of public debt in the world and is in urgent need of making dramatic reforms in its social security system, which now accounts for 33% of the national budget.² A deeper look into Japan's health care revenues and expenditures raises some important questions and concerns about the sustainability of the health care system.

Health Care Expenditures and Government Spending Estimation (Slide 1)

Japan's health care expenditures has continuously grown in recent years, reaching ¥42.6 trillion in 2018.³ An increase in health care expenditures has also been observed in other economies that also have both an aging society and a leading public health care system.

According to the Government, health care spending is anticipated to drastically increase due to Japan's super-aging society (projections are based on estimated annual changes and the increasing cost of goods and wages).⁴ Despite this reality, when controlled for demographic factors, Japan ranks at the lower end of health care expenditures amongst developed nations, pointing to the success of measures aimed at limiting health care expenditures.⁵ Going forward, however, further measures will be necessary to ensure the sustainability of the current *Kokumin Kaihoken* program.

National Burden Ratio Related to Health Care Expenditures (Slide 2)

Over the years, governments have generally passed on certain costs to their citizens as a result of steep increases in providing quality health care. Japan, however, has maintained a relatively low national burden in spite of a continuous increase in its health care spending. In order to achieve this low national burden, the Government has issued sovereign debt to finance increased spending.

Financial Sources of Health Care Expenditures (Slide 3)

A society with an increasingly aging population that does not seek measures for the elderly to finance their own health care or to contribute to the country's overall social security program will inevitably experience a disproportionate reduction in cash flow to pay health care costs (i.e., revenue generated by the Government will decline as a result of a decreasing percentage of citizens that contribute to social security programs). In 2018, 49% of Japan's health care cost was financed by insurance premiums, 38% by taxes (25% by the central government and 13% by local governments), and 11% by out-of-pocket payments.⁶

The portion covered by the central government has been relatively flat at approximately 25% despite the annual increase in health care costs – which will continue to result in a greater amount of spending over time.⁷

Current Policy

With its robust universal health coverage (employees' or national health insurance), Japan applies an age-based, predetermined common co-payment ratio to all citizens, covering all medical care, pharmaceuticals and medical devices officially approved for medical efficacy and safety. Co-payment ratios are currently distributed across multiple age groups: 20% for those under 3 years old, 30% for

those from 3 to 69 years old, 20% for those from 70 to 74 years old and 10% for those 75 years old and above, with certain exceptions based on income limits that were recently passed by the Government for those over 75 years old.

Launch of the “Value-Based Healthcare (VBH)” Proposition

In addition to the biennial revisions of medical fees and reforms of hospital bed functions, Japan has launched the VBH (outcome/performance-oriented model), which includes the introduction of HTA for pricing certain drugs and medical devices. VBH is a health care delivery system in which providers, including hospitals and physicians, are paid based on patient health outcomes. This differs from a fee-for-service pricing model, in which providers are paid based on the number of health care services that are provided. While outcome models have been promoted for over a decade in the United Kingdom, the United States, Canada, and Australia among others, Japan has only recently adapted this initiative. For example, the Government has been exploring criteria to measure and establish values related to the quality of medical treatment provided in hospitals and other medical institutions.

Evaluation of the Public Insurance Framework

Measures to contain the growth of government expenditures through the revision of the public insurance scope of coverage and premiums have been proposed by various stakeholders. For example, the National Federation of Health Insurance Societies (Kenpo Ren) announced its preliminary proposal to exclude hay fever medication from the scope of coverage for the revisions in medical fees in 2020⁸, and now there’s limitation for reimbursement on certain pharmaceutical drugs that can be replaced by over-the-counter drugs and promote the use of less-expensive generic drugs.

Recommendations

1. Promote “Value-Based Healthcare” to increase efficiency

While Japan is in its early stages of introducing VBH, this initiative is limited to the area of pharmaceuticals and medical devices, as seen in the introduction of HTA in the pricing of drugs and medical devices. In the context of the entire health care system, the Government should advance the idea of VBH to establish the relevant infrastructure to maximize efficiencies that is mutually beneficial to the Government and its citizens.

The Government should establish a comprehensive platform to collect, analyze and utilize information related to medical care quality and costs, making it possible to develop substantial incentives to suppliers to promote VBH.

1a. Establish an interactive incentive framework for medical professionals

In order to promote VBH, it is imperative for the Government to ensure that medical practitioners are aware of the need to maximize clinical efficiency. The Government should establish an ecosystem to incentivize medical practitioners to embrace VBH. Accountable Care Organizations (ACO), established within the Affordable Care Act in the United States, provides a relevant example.

An ACO is a government-authorized voluntary institution of doctors, hospitals, nurses, and other medical practitioners that provides primary care while being held accountable for the quality of care and per capita costs.⁹ ACOs place financial responsibility on providers in hopes of improving patient management and decreasing unnecessary expenditures, while providing patients with the freedom to select among various medical service providers. ACOs serve as effective tools to incentivize a variety of medical practitioners to promote better coordination of care delivery and maximize patient care.

2. Reevaluate the co-payment ratios of public insurance

Japan's universal health care program encompasses the same scope of coverage, and related premiums for all citizens. In order to ensure financial sustainability, it is critical for the Government to consider certain revisions to the existing insurance model to improve the efficiency of health care spending. As noted earlier, the Government should also reconsider the proposition of utilizing a co-payment ratio, which at present uniformly provides 90% of coverage to the elderly aged 75 and above, with certain income restrictions. The Government should further consider determining the co-payment ratio based on criteria other than age, specifically the ability to pay.

Other countries have demonstrated reasonable examples of optimizing health care spending by holding their citizens accountable for their own health care.

Private insurance with fixed payments is also common in Japan, which mainly covers co-payments for hospitalization and specialist treatments (such as cancer treatments). These products have essentially become complementary to public insurance.

2a. Adopt phasing premium rates for medications based on their therapeutic value

While the Government uniformly applies the same premium rates to all medications, the Government should consider the alternative of adopting a graduated rate system based on therapeutic value. Graduated rates may also be a means to promote VBH and incentivize the production of medications with higher therapeutic values to generate higher premiums. In France, the public insurance system is a compelling example of how to adopt and deploy a graduated rate system for public health care (Slide 4). An independent scientific committee assesses the therapeutic value, taking into account both the severity of the illness and the efficacy. Therapeutic value is assigned into four levels with different premium rates: "important," "moderate," "low," and "insufficient."¹⁰

If a higher-rated value is assigned, a higher rate of premium is allocated, while no premium is imposed on medications judged as "insufficient." For Japan, an initiative similar to this would assist with promoting VBH by revising these specific aspects of public insurance and accelerate the exclusion of pharmaceutical drugs that can be replaced by over-the-counter drugs, which, as described earlier, appears to be a viable solution to reduce health care expenditures.

2-b. Establish a public insurance framework with diversified coverage of private insurance

In addition to reevaluating and adjusting co-payment ratios in public insurance, it is imperative to also redefine the roles and use of the private insurance system to maximize its value in order to attract citizens to use it. While a cash-based plan for hospitalization and special treatments is the main system utilized in Japan, other countries, such as Germany and France, have been successful in diversifying the functions of private insurance to increase its utilization (Slide 5). These countries have strengthened the supplementary functions of private insurance, and as a result, in France for example, more than 90% of French citizens are currently covered by supplementary private insurance.

Both governments provide options to their citizens for determining their health care needs at the level that is financially suitable for them.

2-c. Establish a new financial framework to enhance individual ownership of health care

The Government should also consider a means for its citizens to take ownership of their own health and well-being from a financial perspective. The introduction of a new financial framework may spur increases in healthier and preventive lifestyles among its citizens. A Health Savings Account (HSA) program, like those established in the United States and Singapore, provides viable examples of how to make it possible. An HSA is an account in which pre-tax money is deposited into a designated account, created for individuals to accumulate funds for use for qualified medical expenses that public insurance would not cover. In the United States, withdrawals from the account are tax-free if used to pay for such qualified

medical expenses. By providing citizens a means to manage their health care costs, it also incentivizes citizens to practice preventive measures to save money on future care. This also ensures that funds deposited into an HSA are held for investment for an individual's future health care needs.

3. Secure necessary financial resources to sustain Japan's universal health care system

In order to ensure the financial sustainability of the health care system in Japan, the Government should consider how to secure sources of revenue to prepare for expected increases in health care expenditures, rather than continuing the current, and possibly unsustainable practice, of financing a significant portion of national health care expenditures through debt issuances.

3-a. Debate the future form of generating governmental income including the use of consumption tax

While the consumption tax increased from 8% to 10% in October 2019, the Government has not clarified its vision for the consumption tax moving forward. The Government should continuously reassess its future plan while carefully considering the results from the increase in tax and provide an overall picture of its plan to its citizens and businesses to restore predictability to the market and ensure an outcome beneficial to all stakeholders.

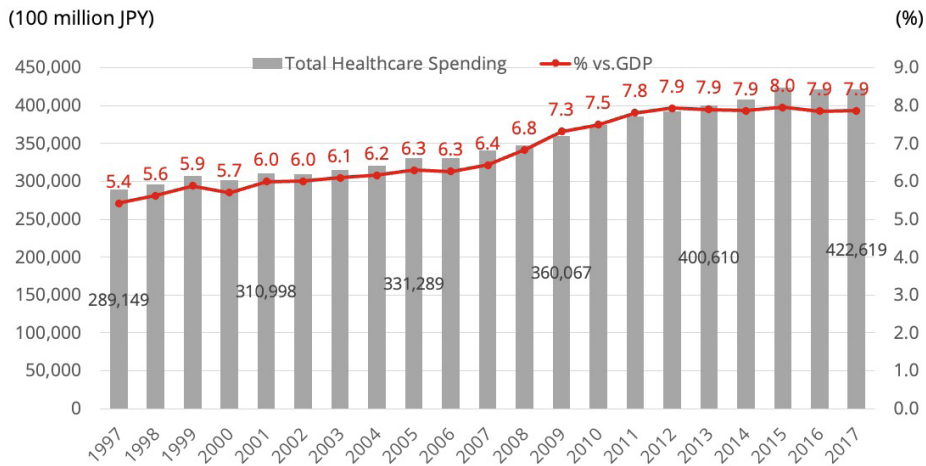
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Slide 1

Increase in Total Healthcare Spending in Japan

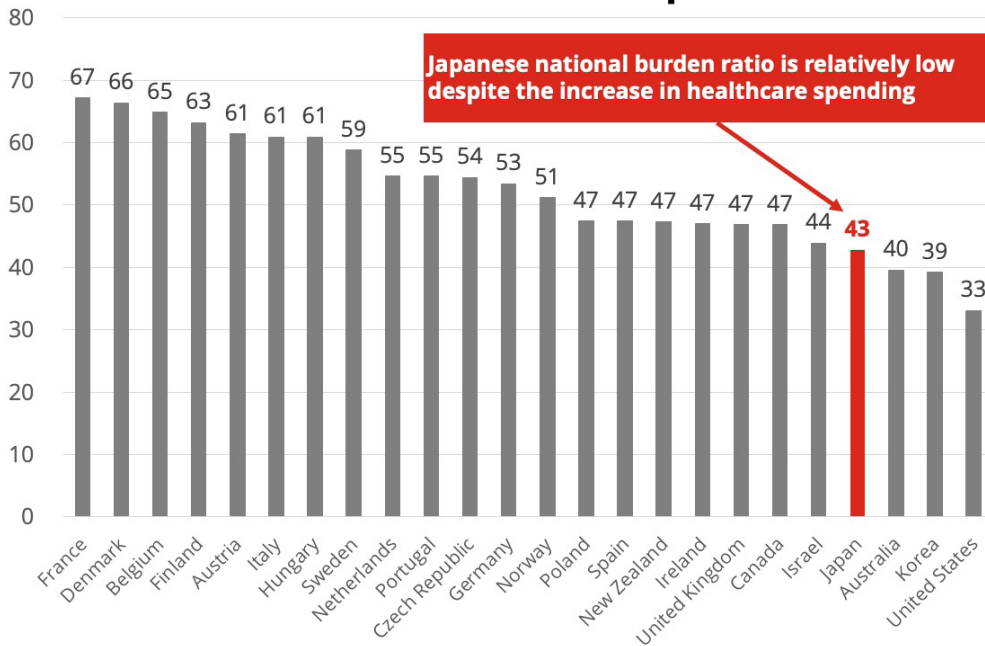
• Total annual spending in 2018 was reportedly **42.6 trillion**, + 0.8% vs. 2017.
 (Though the proportion of healthcare spending vs. GDP was not confirmed, it is expected to be as flat as 2017.)



Source: Japanese Ministry of Health, Labour and Welfare

Slide 2

National Burden Ratio (2016) Related to Healthcare Expenditure



Source: Japanese Ministry of Finance

Slide 3

National Healthcare Expenditures by Financial Sources (%)

	2000	2005	2011	2018
Tax Total	33.2	36.6	38.1	38.6
Central Government	24.7	25.2	25.9	25.4
Local Government	8.5	11.4	12.2	13.2
Insurance Premiums Total	53.4	49.0	48.5	49.1
Employees'	22.7	20.3	20.1	20.8
NHI (self-employed and others)	30.7	28.7	28.3	28.3
Out of pocket payments	13.4	14.4	12.7	12.2
Total	100	100	100	100

Source: Japanese Ministry of Health, Labour and Welfare

Slide 4

France: Graduated Premium Rates for Medications in Public Insurance



An independent scientific committee called the “Transparency Committee” assesses two sets of complex criteria: their therapeutic value and added therapeutic value. The former takes into account the severity of the illness and the efficacy of the drug. **This helps determine its premium rate, ranked by 4 groups with 5 different rates as shown in the table below.** The latter, on the other hand, is measured through a comparison with the clinical benefits of existing drugs or therapies. This is also ranked into 5 groups, exerting a big influence on drug pricing.

■ Graduated premium rates by therapeutic value

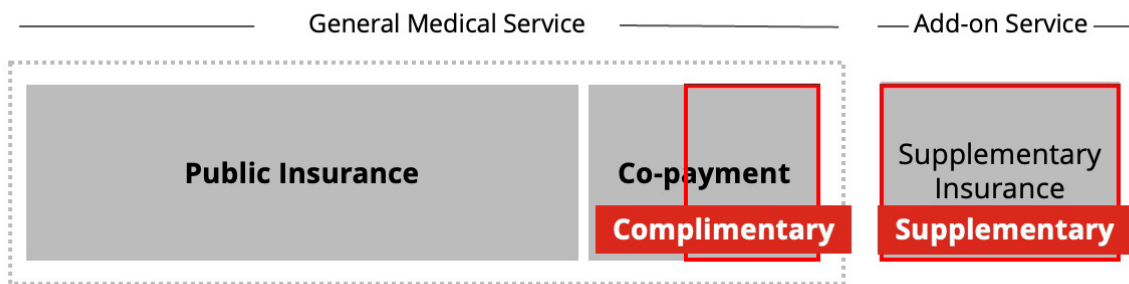
Classification	Premium rate	Examples of medications
Important	100%	Antitumor drugs, immunosuppressants, HIV antiviral drugs, etc.
	65%	Psychiatric and neurological agents, antiepileptic agents, etc.
Moderate	30%	Antihistamines, other allergic drugs, etc.
Low	15%	Gastric ulcer treatment, hypnotic sedative, otolaryngology etc.
Insufficient	0%	Pesticide, antiphlogistic analgesic for skin, etc.

Source: Haute Autorité de Santé (2014) Pricing & Reimbursement of drugs and HTA policies in France

Slide 5

Various Functions of Private Insurance

■ Common Functions of Private Insurance in Germany and France



■ Common Function of Private Insurance in Japan

