Health system sustainability in Japan

Priorities for structural reform



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Executive summary

Japan's healthcare system has kept the country remarkably healthy with relatively minor changes for nearly six decades. The system provides universal care, generous coverage and the most innovative treatments at a cost that is accessible to all.

Yet the very scope of coverage in the Japanese system obscures the extent to which policymakers have put off making necessary but difficult choices. In particular, the lack of regulation of demand for health services, the pressures of an ageing population and the underdeveloped system for evaluating efficiency and effectiveness of medical products and services could paralyse Japan's healthcare system as the cost of state-of-the-art medical treatments increase. The economic consequences of this would inevitably reverberate beyond the health system itself.

Without changes in the incentives built into the current system, Japan will struggle to take advantage of medical innovation and to maintain its ability to deliver high-quality, accessible care in the future. As our *Health system sustainability in Japan* scorecard shows, there are signs that significant fixes to the system may be necessary. Although Japan compares well in many respects to the more expensive and fragmented system in the US, it lags significantly behind the UK and France, and slightly behind neighbouring South Korea, in four of the five principal scoring domains.

Japan's health system compares especially unfavourably with regard to progress in integrated healthcare and research preparedness, but it also has ground to make up in adequate workforce staffing and in the accountability and patient-centredness of the system. At the same time, it scores well in the provision of a long-term care network. We highlight the report's key findings below.

Key findings:

Japan's health financing system is becoming increasingly unsustainable: While the system is justly praised for its extensive coverage, insurance premiums cover less than half of the cost of operating the system with government subsidies filling the gap. Providing innovative interventions that address the needs of Japan's ageing populations is increasingly expensive, and enabling universal access to such innovation requires strategic balancing of innovation, quality and spending.

The country's existing price review process acts as a brake on structural health system reform: Although the biannual price review has kept the system remarkably stable since its founding six decades ago, the political energy it absorbs has made it difficult to implement any significant reforms. The pivot to include concepts of value-based healthcare is required to balance access, quality and cost.

Different incentives are needed to efficiently use medical workforce and hospital resources: Policymakers need to
substantially restructure a system in which prices are kept low,
but there is no limit on the demand for health services. This creates
warped incentives for health providers and leads to an overburdened
workforce that threatens to undermine the quality of care. Additionally,
the use of existing cost-saving generic and biosimilar drugs are not yet
optimised to realise their potential in balancing the health system.

Japan's long-term care system can be a model for other countries but needs better integration with primary care: With the world's oldest population, Japan's long-term care system provides a model of how to care for older citizens, yet as the numbers of older people living with disabilities increases, better integration of the primary and long-term care systems will be necessary to conserve resources.

Japan lags behind developed country peers in the area of research:

Japan does less proprietary research than many other industrialised countries, making it difficult to identify which treatments are worth greater investment. It also needs to develop home-grown health economics expertise to establish a streamlined system for evaluating efficiency and effectiveness of medical products and services, and to accurately identify cost-savings in order to adequately fund innovative treatments and technologies required by Japan's ageing population.

About this report

Health system sustainability in Japan is a report by The Economist Intelligence Unit, sponsored by Pfizer. It examines the challenges and opportunities that Japan's healthcare system is facing and the sustainability of its current system compared with those of other developed industrial countries.

The research uses a scorecard to compare Japan's performance against those of five other countries across a number of domains, including financing, cost-effectiveness analysis, workforce issues, medical research and long-term care.

We would like to thank the following individuals for sharing their insight and experience:

- John Campbell, professor emeritus, LSA Political Science, University of Michigan, Michigan, US
- Yasushi Goto, oncologist, National Cancer Center Hospital, Tokyo, Japan
- Tasuku Honjo, deputy director-general and distinguished professor, Kyoto University Institute for Advanced Study, Kyoto, Japan
- Kenji Shibuya, professor and director of Institute for Population Health, King's College, London, UK
- Yusuke Tsugawa, MD, MPH, PhD is assistant professor of health policy and management, as well as assistant professor of medicine at UCLA.

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Box 1: Findings in context—the unknown impact of the covid-19 pandemic

The covid-19 pandemic, which emerged in early 2020, saw its first confirmed case in Japan in mid-January 2020. By July 2020 there were over 17,000 cases and over 900 deaths in Japan.¹

The vulnerabilities in Japan's health system have been laid bare by the pandemic. Despite the large per-capita number of hospital beds, covid-19 patients have struggled to find hospitals that are able or willing to admit them, as intensive care is only provided in larger centres.² Meanwhile, where elective surgeries have been postponed, hospital beds elsewhere sit empty.³ In early April 2020, the Japanese Society of Emergency Medicine and Japanese Association for Acute Medicine released a joint statement warning of the collapse of the emergency medicine system.⁴

This level of disruption is unlike anything seen before and further highlights the need for reform in Japan's health system to ensure its sustainability in the long term and its capacity to provide adequate care and innovative treatments for an ageing population.

¹ Ministry of Health, Labour and Welfare, Japan. Press release: 新型コロナウイルスに関連した患者等の発生について(6月14日各自治体公表資料集計分). Available from: https://www.mhlw.go.jp/stf/newpage_11871.html (Accessed Jul 2020)

² Financial Times. "Japan's health system exposed as empty hospitals reject Covid-19 patients". Available from: ft.com/content/bo245aa6-871d-4acf-bceo-80a5aac163d6 (Accessed May 2020).

³ Japan Times. "Japan's health care system teeters on the brink as coronavirus takes a toll on hospitals". Available from: https://www.japantimes.co.jp/news/2020/04/29/national/japans-health-care-system-teeters-brink-coronavirus-takes-toll-hospitals/#.Xrjk_WgzaUl (Accessed May 2020)

⁴ Japan Society of Emergency Medicine. "【代表理事声明】新型コロナウイルス感染症に対応する学会員、救急医療関係者の皆様へ". Available from: https://jsem.me/news/post_2.html (Accessed May 2020)

Introduction

Japan's healthcare system is approaching a crossroads. Established in 1961, the system has not changed fundamentally over nearly six decades. Yet an ageing population and growing patient demands are putting pressure on the system like never before.

Japan's healthcare system has developed a reputation for universal coverage and high-quality healthcare delivery. Although most other industrialised countries are facing similar pressures on resources, Japan faces particular obstacles that could undermine its future viability to provide high-quality care. One such challenge is the continued sustainable financing of the system. Insurance premiums and general taxation are increasingly unable to match the escalating costs of state-of-theart medicine, treatment and devices required

to manage diseases associated with an ageing population. This challenge persists despite a unique medical fee review system that allows the government to keep prices in check.

"In terms of cheaper care and life expectancy, we are still one of the best systems in the world, although this is not 100% due to the health system *per se,*" says Kenji Shibuya, professor and director of the Institute for Population Health at King's College London. Japan's health expenditure was 10.7% of GDP in 2018, the sixth highest in the OECD and well above the 8.8% OECD average (see Figure 1).5 "In terms of outcomes, access, cost-effectiveness and efficiency, we are not that bad," continues Mr Shibuya. "[But] it's very hard to maintain all of these goals."

Box 2: What is a sustainable health system?

Sustainable health systems not only have appropriate resources to effectively function but are also capable of keeping up with developments and overcoming hurdles.⁶ Health systems must be able to address challenges and demonstrate the political will required to explore and implement innovative designs for health services.⁷

For Japan, evolving population demographics and financial pressures represent two of the biggest hurdles for sustainability. As this report will outline, Japan must now find policies that maintain the standards of a world-class health system and "balance universal insurance coverage, service quality and financial sustainability."

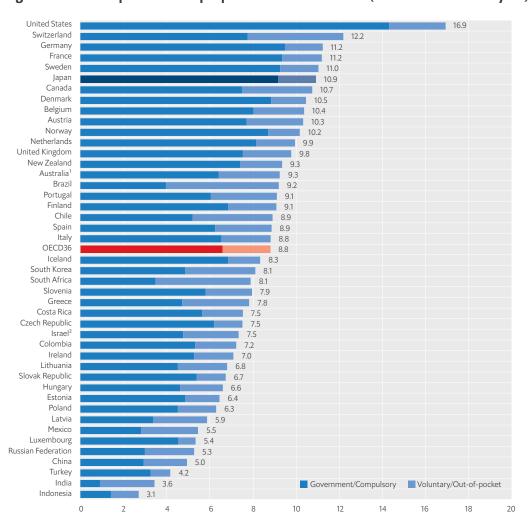
⁵ OECD. "Health at a glance 2019". Available from: https://www.oecd-ilibrary.org/docserver/d58d7923-en.pdf? (Accessed May 2020).

⁶ Braithwaite J et al. "Built to last? The sustainability of health system improvements, interventions and change strategies: a study protocol for a systematic review". BMJ Open, 2017.

⁷ Coiera E & Hovenga EJ. "Building a sustainable health system". Yearb Med Inform, 2007.

⁸ World Health Organization, Regional Office for South-East Asia. "Japan health system review". Health systems in transition, 2018.

Figure 1. Health expenditure as proportion of GDP for 2018 (or nearest available year)



Note: Expenditure excludes investments, unless otherwise stated.

- 1. Australian expenditure estimates exclude all expenditure for residential aged care facilities in welfare (social) services.
- 2. Includes investments

Source: OECD Health Statistics 2019, WHO Global Health Expenditure Database

Cost savings measures such as an increase in the use of generic drugs have historically proved difficult to implement in Japan although great strides have been made in recent years to address this.9 Biosimilars also have room to grow in the Japanese market, according to a recent report by management consulting firm McKinsey & Company, and measures to promote their use are needed to realise savings which can be reinvested into innovative therapies.¹⁰ Japan also conducts less proprietary medical research than many of its industrialised global peers. Consequently, there is little effort to target patients who will benefit most from more costly medical interventions such as gene therapy and immunotherapies.

Better integration of services might also help to streamline Japan's healthcare system and make cost savings. Although Japan has an integrated healthcare strategy, our research finds it has no integrated electronic health records. In addition there are deficiencies in its establishment of a distinct and discretely funded primary care system. Paradoxically, salary incentives in Japan are skewed towards general practice rather than secondary care. This has the potential future advantage of offering a better platform for preventive care but also underscores one of the costlier incentives of the system: Japanese patients have one of the highest rates of physician visits per annum in the world.

At the same time, Japan's mandatory longterm care insurance has put it ahead of many countries in Europe and North America in terms of caring for its elderly population and introducing innovative ways of keeping old people independent.

Making Japan's system sustainable for the long term will involve difficult choices for it to continue to do what it does well-offering high-quality, affordable care—while bringing innovative care to patients in priority health areas. The latter is vital for Japan to manage the health needs of its ageing populations, such as complex cancers and neurological diseases. Indeed, Japan's share of spending on specialty drugs, such as innovative oncology medicines, is expected to grow from around 30% in 2018 to 41% in 2023.11 If funding is to be available for the research, development and universal access to such innovations, strategic cost control measures are needed to balance innovation, quality and expenditure.

⁹ Ibid. Ref 8.

¹⁰ M Kim, et al, "Understanding the Opportunity in Japan's Biosimilar Market," McKinsey & Company, September 20, 2019.

¹¹ Iqvia. "The Global Use of Medicines in 2019 and Outlook to 2023". Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023, (Accessed May 2020).

Chapter 1. The health systems sustainability scorecard

Our scorecard compares the performance of Japan's healthcare system with that of five other OECD economies: The US, the UK, South Korea, France and Germany.

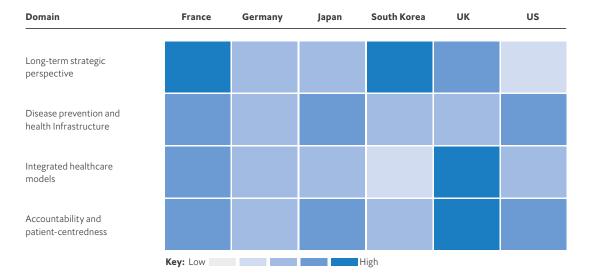
The countries were given scores across five main domains: long term strategic perspective; disease prevention and health infrastructure; existence of integrated healthcare models; accountability and patient-centredness; and research readiness. The scorecard also includes a number of sub-domains.

Overall, Japan ranked in the lower tier of the six study countries (see Figure 2 for topline findings and Appendix 1 for full results).

Japan's system received the highest ratings for 'disease prevention and health infrastructure' and 'accountability and patient-centredness'. It scored lower in 'long-term strategic perspective', lacking comprehensive policies for biosimilars.

Japan's worst performance was in the domain looking at the existence of integrated healthcare models, due in part to the absence of a distinct primary healthcare system in the country. The scorecard also highlights the absence of integrated electronic medical records in Japan. The country was also comparatively weak in accountability and patient-centredness, which looked at national

Figure 2. Overall domain-level results in the health systems sustainability scorecard



Note: The fifth domain 'Research readiness' is a quantitative un-scored background indicator. Refer to Appendix for further details Source: The Economist Intelligence Unit

plans and policies, civil society participation in health policy decision-making and the existence of patient-centred policies.

The full scorecard methodology and country scoring is shown in Appendix 1. In order to accurately interpret the findings from the scorecard, some important limitations should be considered.

- For each domain, available data were collected to best reflect the local situation while allowing for standardisation and comparison across markets. In aiming for comparability, some specificity and context may be lost.
- Where possible, data are derived from official or government sources; however, the source of data and homogeneity of definitions used by different sources must be considered.
- The scorecard does not aggregate scores to rank markets either in each domain or overall; scores can only be compared with caution across indicators.

Chapter 2. State of play: How Japan's health system works now

Japan has much to be proud of with regard to its universal health system. Established in 1961 as part of the country's effort to create a post-war consensus based on egalitarianism and prosperity,¹² the system is affordable and comprehensive in its benefits for end-users. This has contributed to Japan having the highest life expectancy among OECD states in 2017 at just over 84 years.¹³ The system has remained relatively unchanged over the past six decades despite great advances in both technology and delivery of care.

While our scorecard shows that, on the surface, Japan's health system fares well in terms of provision of care and long-term strategic perspective, analysis of the individual elements of this expose vulnerabilities related to ongoing financial provision. "Politically, it has become hard for Japan to make structural changes to their health system, because the basic structure of the ways it is financed was developed right after the second world war, and it has undergone a number of incremental changes since then" says Yusuke Tsugawa, assistant professor of medicine and health policy at the University of California, Los Angeles. Indeed, current discussions about the need to reform Japan's health system are similar to those that were taking place in the 1970s, according to John Campbell, a professor emeritus of political science at the University of Michigan.

In 2015, a government advisory panel published the Japan Vision: Health Care 2035 report that proposed to restructuring the healthcare system along three key principles: **implementing value-based healthcare**; **empowering society and supporting personal choice in healthcare**; and **leading and contributing to global health**.¹⁴

The report also highlighted the need to accelerate investments in innovation (including the establishment of a platform for clinical trials and establishment of secure research funding), better use of data to link the healthcare network and help with disease management and policy evaluation, more sustainable financing and better training of more healthcare professionals.¹⁵

Little emphasis has been put on these proposals since the report's publication, and the structure of the existing finance system has made many of these goals especially challenging to fulfil. Tasuku Honjo, deputy director-general and distinguished professor of the Kyoto University Institute for Advanced Study and a 2018 Nobel laureate in Medicine, considers the Japanese system to be "very socialistic" in terms of its overall access and willingness to cover most new medicines at prices that are affordable to patients. Alongside the unwillingness to put any limits

¹² World Health Organization. "Japan Health System Review". Health Systems In Transition, 2018.

¹³ Ibid, Ref 8.

¹⁴ Japan Ministry of Health, Labour and Welfare. "Japan 2035: Leading the World Through Health". Available from: https://www.mhlw.go.jp/seisakunitsuite/bunya/hokabunya/shakaihoshou/hokeniryou2035/assets/file/healthcare2035_proposal_150703_summary_en.pdf (Accessed May 2020.

¹⁵ *Ibid*, Ref 14.

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on end-of-life care for the elderly, this poses a "big burden to the economy" he says.

"We call this health insurance, but it is not really insurance because the system is already bankrupt," Mr Honjo says. "Japanese governments inject huge amounts of money into the system." Health spending, he adds, is already consuming a significant part of Japan's national budget.

Indeed, those interviewed for this report say the real concern is that the health system is so intricately linked to the rest of the economy that any financial crisis it suffers could have a knock-on effects elsewhere.

"The healthcare system is weighing so much on the whole economy that if it collapsed the whole economy would collapse," says Yasushi Goto, an oncologist at the National Cancer Center hospital in Tokyo. "There are social conflicts between each group because we are now paying too much but some patients need better treatment. Everyone is thinking that this is a problem, but no one wants to solve it because it will hurt everyone."

Chapter 3. The financing conundrum: Price setting and review

Under Japan's social insurance system, healthcare is sustained by three separate funds: a social security tax to which individuals and employers each contribute, out-of-pocket costs shouldered by patients and subsidies from the national government or prefectures (regional authorities).

This latter portion amounts to 40% of the total health budget, currently around ¥40trn, according to Dr Goto. "The shortage in the budget is covered by generic taxes," he says. "No one really suffers from the raising of costs, but we never raise the social security tax or over-the-counter payments."

Annual deficits have become a normal part of Japan's health financing system, and despite the regular price review most people in Japan think they are paying too much for their care. "Since the 1960s, Japan has been making incremental changes to its healthcare financing system—for example, changing co-payment or fee schedules—while avoiding major reforms. The Japanese government has been micro-managing prices for every single healthcare service covered by their social health insurance" Mr Tsugawa says. "The problem is that they only control prices, and the quantity of care is basically uncontrolled"

This structure also enshrines governmental power and control over the system, interviewees say. "The national fee schedule is one of the few levers Japanese government

use to control the entire health system, and they do it so well that they are probably reluctant to use different approaches," Mr Tsugawa comments. "If change doesn't work out, they can use the lever again and again."

Mandatory price reviews

The price adjustment mechanism for Japan's healthcare system is the biannual price review. Its key role, according to Mr Campbell, can be likened to a structure based on "many pipes, but one faucet, and the faucet is the fee schedule, revised every two years for every treatment, for every price listed". Meanwhile the government of Japan has recently approved plans to switch to an annual price review from April 2021, adding further administrative burden to the system.¹⁶

The rolling back of prices for medicines and doctors' visits on a biannual basis isn't matched by similar curbs on demand for health services. This gives doctors in Japan's fee-for-service system a perverse incentive to double down on office visits and procedures in an effort to make up for lost revenues. The pricing pressures also affect hospitals, many of which have gone bankrupt in recent years.

"The price review is a big deal," Mr Campbell says. "It's heavily covered in newspapers and takes six to eight months." Under the review the government decides which treatments will be provided and for what conditions.

¹⁶ PHARMA JAPAN. "Japan Govt Adopts 2020 Honebuto Policy, Drug Price Survey to Be Conducted This Autumn". Available from: https://pj.jiho.jp/article/242537 (Accessed Jul 2020).

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Meanwhile, the effort put into the review process and its effective use as a valve to reduce existing pressures on the system make it difficult to undertake more substantial change. "The call for radical reform has been continuous," Mr Campbell explains. "People always say it should happen, and this has been a constant for thirty years, but all of the political energy goes into the price review process."

In fact, he adds, one strong point of the Japanese system is that it has hardly changed at all in a substantial sense while still incorporating new technology and new innovations within the existing system. In contrast with more radical overhauls the Japanese system has remained stable over the decades. The resulting efficiency, along with Japan's relatively healthy diet and lifestyle, have made for a healthy population at relatively low cost. What is less clear is how long this can continue. After all, the Japan Vision: Health Care 2035 report recognises that "relying on financial adjustments to maintain the current system will no longer suffice".17

Chapter 4. Structural issues: Primary versus secondary care, long-term care and poor incentives

Those interviewed for this paper note that the nature of the price review in Japan creates unintended incentives that distort the system in a number of different ways.

Distorted incentives for primary care

Because the review process frequently revises prices downward without limiting demand for services, health providers are forced to scramble to make up the difference. This is easier in primary care where doctors can order tests and prescribe even basic medicines to help make ends meet. Japanese citizens have one of the highest numbers of annual visits to physicians of any country in the OECD with an average of nearly 13 visits a year, second only to South Korea. For elderly patients, the rate can be even higher at 20 to 30 times a year.¹⁸

"The unintended consequences of using the fee schedule and lowering prices is that healthcare providers have been responding by increasing the quantity of care, in order to avoid deficits" Mr Tsugawa comments. For example, with the price to see a doctor set extremely low at around US\$7 per visit, physicians prescribe blood tests and prescriptions on a regular basis for most patients; "operation costs of hospitals and clinics are expensive, and it is the only way for them to raise sufficient revenues to avoid bankrupt."

Efforts to introduce capitation payments or a bundling system for primary care have also stalled with the result that there is little incentive to improve preventative care. The lack of controls on access to specialists also contributes to inefficiencies and waste, interviewees report.

"In terms of free access to any level of care, right now instead of the strict system in the UK there is huge demand and patients tend to go to big hospitals and waste the available resources," says Mr Shibuya. Despite the likely opposition of physicians to the introduction of a capitation system, he adds, legislation due to come into effect in 2025 to integrate preventative and long-term care at the municipal level could force the issue.

Pressures on tertiary care

Mr Shibuya and others interviewed agree that there are too many hospital beds currently being used for chronic care. The government is trying to reduce these numbers and transfer to long-term care and rehabilitation services.

Demands on the system have led to high levels of burnout among healthcare providers, interviewees report. This factor has contributed to a shortage of health workers including doctors and, most notably, nurses. The nursing shortage poses particular challenges given the high care needs of Japan's ageing population.

¹⁸ OECD Data, Doctors' Consultations per capita 2018. Available from: https://data.oecd.org/healthcare/doctors-consultations.htm (Accessed May 2020).

"There is no question that there is overuse and waste [in the primary care system]," says Mr Campbell. "On the other hand, many expensive procedures are rather unprofitable—surgery rates are low compared to many other countries." The average income of general practitioners, who are self-employed, is higher than that of hospital specialists who work on salary. This is the opposite of the usual pattern in other developed countries, he adds.

With profits primarily generated in the primary sector, even large university and public hospitals struggle to stay afloat in Japan and hospital specialists suffer from overwork and burnout. Japan currently has just 2.4 physicians per 100,000 population, lower than in many other OECD countries.¹⁹

Japan's prime minister has been looking to institute workstyle reforms for physicians, Mr Shibuya notes. Legislation introduced in April 2019 aims to gradually reduce the maximum number of overtime hours to 100 a month, by 2024. Yet emergency medicine doctors and those from some specialities are exempt from the cap, many of whom regularly work up to 2,000 overtime hours annually.²⁰ Extending the cap will involve structural reforms, including greater integration of the health system, differentiation between hospital responsibilities and better preventative care.

This, in turn, raises new questions about the healthcare financing system. "There are issues about how much public services will cover in

terms of care and whether to stick with a taxsubsidised universal social insurance scheme or introduce an element of private coverage," Mr Shibuya says. The evolution of extremely innovative but expensive medicines, especially in the area of oncology, has raised particular questions about how much the system can cover. "The current health insurance package is very generous and we are trying to include everything, but because of cutting edge technology, which is more expensive, there are questions about whether it should cover everything."

Some of this funding would be better off targeted to more preventative care in an effort to instruct patients on how to avoid lifestyles that put them at risk of chronic conditions, according to Mr Honjo. In addition, Japanese insurance coverage should stop funding simple over-the-counter medicines available at pharmacies and people should be encouraged to buy private supplemental plans where they can, he adds.

Long-term care

Japan's ageing population clearly poses some of the biggest challenges facing the country's healthcare system. The associated financial burden, the need to move from independence to support in communities and the increasing and diverse demands from the patient side of the equation are all taking their toll, Mr Shibuya says. Japan received full marks in our scorecard for the existence of a separate system of long-term care insurance.

¹⁹ *Ibid*. Ref 18.

²⁰ Japan Times. "Effort needed to reduce doctors' working house". Available from: https://www.japantimes.co.jp/opinion/2019/01/31/editorials/efforts-needed-reduce-doctors-working-hours (Accessed May 2020).

Although a healthier lifestyle has benefitted older Japanese people, once they age they are still likely to require more healthcare services, according to Mr Tsugawa. In particular, he notes that the Japanese population, like other East Asian countries, has higher smoking rates and are more susceptible to strokes. This makes them more likely to develop disabilities that will require more intensive long-term care. "Even if we can reduce conditions like stroke and diabetes, it is estimated that the overall trajectory doesn't change dramatically, because Japanese people are already healthy, and therefore, there is little room for improvement." Mr Tsugawa says.

All Japanese citizens must take out mandatory long-term care insurance. The system is public, and Mr Campbell describes it as "probably the most devolved system in the world outside Scandinavia—everyone aged over 40 pays a premium, and everyone aged over 60 is eligible for it." The benefits range from institutional and nursing home care to highly-developed home and community care.

More elderly people in Japan attend adult day care than receive home care under a system based on assessment of a person's proficiency in Activities of Daily Living (ADLs). In this sphere, Japan has undertaken some innovative and successful projects, Mr Campbell notes. "There is an interface between social care and medical care, and the big policy reform effort in Japan over the last five or six years has been to try to integrate the systems a little more, at the community level." he says. "[The government] wants more people treated at

home so they give bonuses to doctors who do more home visits."

The growing need for additional funding as Japan's population continues to shrink and the proportion of those over the age of 65 increases is one of the main issues occupying the minds of policymakers who have contributed to the country's 2035 strategy.

In addition to the focus on integrating services for the elderly, Japan is also a leader in experimenting with the use of robots and artificial intelligence (AI) to help with older patients with movement difficulties. "I think we have to introduce robotics to help support elderly people," Mr Honjo explains, citing the examples of Cyberdyne and Sugawa Kuroda Laboratory at Tohoku University as organisations working on the cutting edge of this area.

Yet funding for elderly care will have to be balanced against support for healthcare innovation. This will require more careful analysis of how to get the most value out of healthcare investment, those interviewed agree.

New medical technologies

Between 2010-2015, the Ministry of Health, Labour and Welfare (MHLW) addressed the so called 'drug lag', where Japanese patients experienced a delay in accessing the latest treatments. Key to achieving this was the adoption of regulatory and pricing policies - such as the *Sakigake* fast-track regulatory

approval. Consequently, reimbursement to new drugs dropped to an average of 60 days after regulatory approval by 2011.

Spending on medicines remains flat, largely because the government has introduced policies to increase the use of generic medicines, or those treatments no longer protected by patents.

The uptake of generics was noticeably slow in Japan prior to 2015 policy intervention from the MHLW which included incentives based on volume-based generic conversion targets.²¹ Generic use has risen from under 50% volume share in 2013 to 77% in 2019, according to the Japan Generic Medicines Association.²² The use of generic drugs in Japan reduced 2019 expenditure by ¥1,398.7bn (around US\$12.8bn), while biosimilars only accounted for ¥14.6bn of this (around US\$134m).

In 2015, the market penetration of biologic medicines was only around 10% in Japan versus around 30% globally.²³ It is not surprising, therefore, that Japan had the second fastest growing market overall for biologics in 2019.²⁴ The uptake of biosimilars has been slow with the exception of molecules such as filgrastim and epoetin-alfa where hospitals had been incentivised to prescribe.

These two molecules, along with insulin glargine, accounted for 80% of sales in Japan in 2017 compared with around 55% globally, according to a 2019 report from McKinsey and Company.25 While the government's conversion targets apply to biosimilar products, the impact on encouraging their use has clearly not been seen. Strictly volume-based targets results in prioritisation of the most frequently-used products for conversion to a generic, regardless of cost or value. Biologics—which are relatively lessfrequently used but are more costly—are not often addressed. Further policy intervention is now being implemented to better encourage the use of biosimilars. In early 2020, Japan's Central Social Insurance Medical Council (known as Chuikyo) issued recommendations for reimbursement reform in the 2020 budget. This was followed by an introduction of a new fee schedule by MHLW intended to incentivise the use of biosimilars and increase biosimilars spending which stands at ¥22.6bn as of March 2020.²⁶ The new fee schedule includes a ¥1,500 (around US\$15) billable physician fee "for the instruction and management of self-administered injectables" with a limited range of biosimilars covered including insulin, human growth hormone, teriparatide and etanercept.²⁷ Whether these limited measures

²¹ Ryosuke Kuribayashi, et al. "Current Japanese Regulatory Systems for Generics and Biosimilars". Journal of Pharmaceutical Sciences, 2018.

²² Japan Generic Medicine Association. "Generic Share (%) investigated by JGA and IQVIA Japan". Available from: https://www.jga.gr.jp/library/pdf/media/120326152352.pdf (Accessed Jun 2020).

²³ JETRO. "Market report biopharmaceuticals and biosimilars, December 2017". Available from: https://www.jetro.go.jp/ext_images/en/invest/attract/pdf/mr_bio_en201712.pdf (Accessed May 2020).

²⁴ The Pharma Letter. "Japan looks to open doors to healthcare innovation". Available from: https://www.thepharmaletter.com/article/japan-looks-to-open-doors-to-healthcare-innovation (Accessed May 2020).

²⁵ McKinsey & Company. "Understanding the Opportunity in Japan's Biosimilar Market". Available from: https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/understanding-the-opportunity-in-japans-biosimilar-market (Accessed May 2020)

²⁶ Japan Ministry of Health, Labour and Welfare. "Overview of NHI price revision" Available from: https://www.mhlw.go.jp/content/12404000/000613996.pdf (Accessed May 2020).

²⁷ Pharma Japan. "Chuikyo Issues Recommendation for 2020 Reimbursement Reform; Biosimilar Premium Set at 1,500 Yen per Month" Available from: https://pj.jiho.jp/article/241502 (Accessed Mar 2020).

are enough to encourage the uptake of biosimilars with the same success seen with generic drugs in Japan remains to be seen and the Japanese government may need to consider additional incentive systems to cover all biosimilar use cases.

Additional efforts to educate physicians and patients in Japan around the science and regulation of biosimilars should also be considered, taking example of similar efforts by the European Medicines Agency and US FDA in 2017.

Since 2018, the MHLW has been considering policy options to manage the introduction of new high-cost medical innovations.

This included the development of a cost effectiveness assessment system in 2019.

Expansion of these policies risks reducing the speed at which patients access these treatments and also limit physician choice.

Thus, new thinking could be encouraged to develop novel value-based pricing and payment methods. To date, there has been limited progress on the advancement of such approaches in Japan.

Chapter 5. Looking forward: Policy interventions for long-term sustainability

Many of the potential fixes for these distorted incentives could have a negative impact on the health system's performance and hurt the quality of care, interviewees point out. Tighter control over the demand for healthcare services could cause hospitals to go bankrupt, Mr. Tsugawa notes. "In order to effectively control the quantity of care provided, Japan needs to consider moving to a capitated payment combined with pay for performance for the outpatient care.

Ultimately, Mr Tsugawa observes, there is unlikely to be a rapid implosion of the system in 2025 even if no further changes are made. Yet many of the consequences of the current system—including overwork of Japanese physicians—are likely to deteriorate further, making it harder for hospitals to work effectively and continue to provide high-quality care.

Reassessing value and efficiency

Along with Japan's nascent pharmacoeconomic requirements, the adoption of broader concepts of value in healthcare—such as outcomes-based pricing—is still in its infancy. Indeed, there is not yet clarity on which performance indicators the system should adopt to define value, and how it will quantify the value of incentives to encourage further efficiency.

It is also incumbent on the government to define ways of measuring quality of care, if the goal of moving from a volume-based to a value-based system is to be realised. Given the existing demands on the system, the government will have to find new ways of financing healthcare spending or free up funds using other methods to ensure access to innovative healthcare solutions. Attempts to increase patient co-pay or limit access to drugs or services that are assessed as 'low value' are likely to be met by vocal opposition. Innovative pricing and financing models, such as risk-based, subscription, or an amortization 'mortgage' model remain untested in the Japanese system.

This ultimately requires a change of thinking around the concept of cost and value for policy makers, physicians and patients.

Evidence-based policy making

"Japan is at the tipping point where it needs to think seriously about having a major reform, but they don't have scientific evidence necessary to design a robust health system," Mr Tsugawa says. "We need a sufficient number of health policy researchers and health economists who understand both theory and evidence required to design health system —however, unfortunately, there are only a small number of such researchers in Japan."

The country has also failed to invest sufficient resources in data generation to create an evidence-based system. Instead of investing in healthcare policy research, the country has relied on political solutions. Policymakers need to find a way of lowering overall healthcare spending without jeopardising

quality. For the government to accomplish this task, it needs to identify those services that should be covered by the government, and this will require sufficient claims data.

The good news, Mr Tsugawa says, is that younger policymakers in Japan's parliament are increasingly interested in looking at evidence-based policymaking. The bad news is that the research and establishment of a cost-assessment infrastructure will take time, and the window is likely to close by 2025. "There are people in the leadership positions who are foreseeing the problem, looking for evidence-based solutions, and starting to fund policy research."

A panel under the minister of state for economic and fiscal policy is looking at reform for a *social security system oriented* to all generations, and is due to release final recommendations at the end of 2020.

Conclusion

Japan's healthcare system is rapidly reaching a crossroads as mounting demand for services and an ageing population put increasing and unsustainable pressures on the existing infrastructure and financing mechanisms.

Japan's system can boast of tremendous progress in providing universal, affordable, high-quality care to its population for more than half a century. Now, policymakers need to ensure that the system remains viable for future generations.

Reviewing the price setting mechanisms and the unintended inefficiencies that it promotes is the first step to giving the health system greater stability. Following this, the more efficient use of available resources—including the wider use of generic medicines and addressing the low penetration of biosimilars—will offer opportunities to keep the health system balanced in the long term. These approaches are even more prescient given the unfolding impact of the covid-19 pandemic. Creating an effective system for producing evidence-based analysis is also crucial for Japan to get health costs under control and make the best use of limited resources. Finally, better integration of the healthcare system will help boost long-term care to Japan's elderly citizens while at the same time reducing pressures on its overburdened medical workforce.

Appendix: Scorecard methodology and country scoring

Domain	Indicator	Aim/Rationale
1. Long-term strategic perspective	1.1.1 Govt. Spending on Health	To assess the government spending on health
	1.1.2 Population Covered by Insurance	To assess the coverage of the population by some form of insurance
	1.1.2 Population covered by Insurance	To assess the coverage of the population by some form of insurance
	1.1.2 Population covered by Insurance	To assess the coverage of the population by some form of insurance
	1.1.3 Cost Effective use of health care resources and investments	To assess whether the country is undertaking any healthcare cost control measures in order to maintain health budgets
	1.1.3 Cost Effective use of health care resources and investments	To assess whether the country is undertaking any healthcare control measures in order to maintain health budgets
	1.1.4 Healthcare cost control measures	To assess whether the country is undertaking any healthcare control measures in order to maintain health budgets
	1.1.4 Healthcare cost control measures	To assess whether the country is undertaking any price control measures in order to maintain health budgets
	1.2.1 Pharmacoeconomic evaluation	To assess whether the country has robust health technology evaluation policies
	1.2.2 Regulatory policies	To assess whether the country has robust regulatory policies for innovative technologies
	1.2.1 Existence of long term strategic policy	To assess whether the country has a long term strategy on health
2. Disease prevention and health infrastructure	2.1.1 Existence of National Prevention Programs	To assess the status of prevention programs in the country
	2.2.1 Adequacy of health workforce	Adequate number of trained healthcare professionals are required to maiantain the population in good health
	2.2.2 Life-long Development of Health workforce	Healthcare professionals require to update their skills over time in order to care for the population in the future
3. Integrated healthcare	3.1.1 Primary Healthcare System	A strong primary care system has been found to be important to a sustainable healthcare system
models	3.1.2 Primary Healthcare System	A strong primary care system has been found to be important to a sustainable healthcare system
	3.1.3 Integrated Health	To assess whether the country has a policy on the need for integrated health services delivery
	3.2.1 Electronic Health Records	Electronic healthcare records are a significant component of a sustainable healthcare system
	3.3.1 Reduction of unwanted variation	To assess an aspect of safety and quality of the health system
4. Accountability and patient centredness	4.1.1 Availability of National Plans and policies	To assess whether the health system is transparent in making its plans and strategies easily accessible by the public
centreuness	4.1.1 Availability of National Plans and policies	To assess whether the health system is transparent in making its plans and strategies easily accessible by the public
	4.2.1 Civil Society Participation	To assess participation of civil society in health policy decision making
	4.3.1 Patient Centred Policies	To assess the patient centric nature of the health system
5. Research readiness	5.1.1 Public spending on Research	To assess the public spending on research
reaumess	5.1.2 Public spending on Research	To assess the focus of public spending on health research

Domain	Question		Scoring		Germany Japan South Korea UK				US
1. Long-term strategic perspective	What is the government spending on health as a percentage of GDP?	Quantitati	ve	9.3%	9.5%	9.2%	4.8%	7.6%	14.3%
	What is the percentage of population with public health insurance coverage?	Quantitati	ve	99.9%	89.4%	100%	100%	100%	35.9%
	What is the percentage of population with private health insurance coverage?	Quantitati	ve	0.1%	10.6%	0%	0%	0%	54.9%
	What is the percentage of the population with voluntary private health insurance?	Quantitati	ve	96%	24%	90%	68%	10%	8%
	Does the country have a national policy on generic substitution?	Yes=1 No=	=0	1	1	1	1	1	0
	Does the country have a policy for the adoption of follow-on (also called 'me-too') drugs?	Yes=1 No=	Yes=1 No=0		1	1	0	0	0
	Does the country have a policy on mandatory price reduction of drugs?	Yes=1 No=	-0	1	1	1	1	1	0
	Is long-term care separated out from the national insurance system?	Yes=1 No=0			1	1	1	0	0
	Does the country require mandatory pharmacoeconomic evaluation before new drugs get reimbursed through the public system?	Yes=1 No=	1	0	0	1	1	0	
	Does the country have a regulatory policy on biosimilars?	Regulatory	No regulatory mechanism = 0 Regulatory mechanism but poor adoption of policy = $+1$ Regulatory mechanism with good adoption of policy = $+2$		2	1	2	2	2
	Does the country have a national strategic health plan/policy published within the last 5 years?	Strategic p Policy upd No policy o	2	0	1	2	2	1	
2. Disease prevention and health infrastructure	Are there national prevention programs for a) HTN, DM, HF, Stroke b) Cancer c) Mental health conditions	If Yes for If No a/b/c	a) = +1 b) = +1 c) = +1 = 0	3	1	3	3	3	3
	Are there adequate numbers of trained healthcare professionals for the population (based on OECD avg)?	Above OE	Above OECD Avg for nurses = +1 Above OECD Avg for physicians= +1 Below OECD Avg for Physicians/Nurses = 0			1	0	0	1
	Is there evidence of quality training and skill upgrading for HCPs	Yes = 1	No = 0	1	1	1	1	1	1
3. Integrated healthcare	Does the country have a distinct primary healthcare system?	Yes = 1	No = 0	1	1	0	0	1	0
models	What is the percentage of government health spending allocated to primary healthcare?	Quantitati	Quantitative		Data not available		Data not available	6.00%	Data not available
	Does the country have a policy or strategy on integrated care?	Yes = 1	No = 0	0	0	1	0	1	0
	Does the country have national integrated electronic health records?	Yes = 1	No = 0	2	0	0	1	2	1
	Does the country publish an atlas or statistics on unwanted variation(medical practice pattern variation that cannot be explained by illness, medical need, or dictates of evidence based on medicine) to guide system and service improvements?	Yes = 1	No = 0	1	1	1	0	1	1
4. Accountability and patient centredness	Are the country's national health plans and policies available publicly on websites or other medium?	Yes = 1	No = 0	1	1	1	1	1	1
	Do the national plans have defined timelines or milestones, or published annual reports?	Published	ed timelines or milestones =+1 annual reports =+1 e above = 0	2	1	2	2	2	1
	Is there evidence of the participation of civil society in health policy decision making or HTA processes in the country?	Yes = 1	No = 0	1	1	1	1	1	1
	Does the country have a policy on shared decision making or patient centredness?		hared decision making =+1 atient centredness =+1	1	1	1	0	2	2
5. Research	What is the percentage of GDP spent on research in health?	Quantitati	ve	2.2%	0.35%	0.50%	0.13%	0.08%	0.22%
readiness	Of the total public expenditure on health research what is percentage spent on basic science vs translational research?	Quantitati	ve		Data not available		35.72%		Data not available
	What is the number of public funded research agencies in the country?	Quantitati	VP.	34	40	29	5	19	42

Scorecard domain weightings

Domain	Scoring range	e				
Long Term Strategic Perspective	0-9	0	1-3	4-6	7	8-9
Disease Prevention and Health Infrastructure	0-6	0	1-2	3-4		6
Integrated healthcare models	0-5	0	1	2-3	4	5
Accountability and Patient centredness	0-6	0	1-2	3-4	5	6

Priorities for structural reform

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