Case study

Japan

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Price setting and price regulation in health care: Japan

The following aspects should be noted when reforming the payment system. First, services are determined not only by the patient's needs, but also on how the needs are interpreted by the physician. As Fig. 1 shows, the definition of "appropriate" differs according to the physician's education and training, the resources available (big urban hospital or rural clinic), and the method of payment (fee-for-service or fixed salaries). Thus, it would be difficult to define an "appropriate" package of services that meets the needs of every patient.

Figure 1
Defining appropriate treatment

"Appropriate" depends not only on the patient, but also on:

1. Each physician's experience, including education, training, and encounters with patients. This tends to be idiosyncratic.
2. Where the physician practices, whether in a rural clinic or a big urban hospital.
3. How the physician is paid, whether FFS (leading to expansion of need) or more inclusive payment leading to a contraction of need.

Source: author.

Abstract

Second, even if there is agreement on the services and the amount of time required, there is no consensus on how much physicians should be paid relative to the average worker for delivering the services. Should their income be twice or ten times that of the average worker? There are big differences in this ratio even among high-income countries (Conover, 2013). The labour costs of nurses and other allied health care workers, and the extent of task-shifting, also vary across and within each country. The national average is often used, but whether the current levels should be maintained is disputed from those within and outside the health care sector.

The above implies that payment reform should focus less on economic theory and data from cost studies, and more on negotiations with physicians and hospital organizations. Japan once tried to radically redesign its payment system. A huge cost

study was made in 1950, in which truck-loads of data were collected. However, it was not possible to set fees according to the standard cost of each service item, because costs varied greatly across hospitals (Matsuura and Oomura, 1983). Moreover, the government and the Japan Medical Association (JMA) had very different ideas on how much physicians should be paid on an hourly basis when compared with average workers. Since then, the government has relied mainly on structured negotiations with the JMA and other provider organizations in setting and revising fees.

The two major goals pursued by the government have been containing costs and nudging providers towards policy goals, such as decreasing the lengths of hospital stays and promoting home and community care. Whether costs have been contained is debatable. Total health expenditures to the GDP are 10.7%, the sixth highest ratio in the world (OECD, 2018). However, the fact that Japan has the highest percentage of elders 65 and over in the world (27.7%) and that expenditures for long-term care (LTC) are relatively high (Campbell et al., 2016) should be taken into consideration.[1] The lengths of hospital stays are still long, but many "hospitals" in Japan are de facto nursing homes. Regarding quality, the macro indices of health are excellent, and the outcomes for specific clinical conditions are the same or better than those reported for other countries (Hashimoto et al., 2011). This report will explain how the payment system functions to provide possible lessons to other countries.

1 The percentage of total health expenditures (THE) to GDP jumped from 9.2% in 2010 to 10.6% in 2011. This occurred only in Japan and is probably due to the fact that virtually all LTC insurance expenditures were first included in THE from 2011 (IHEP, 2016).

1
Historical development

Before and after Western influence

Payment reform should take a historical perspective because the physician's behaviour and values have been rooted in the past. In Japan, private practitioners were well established by the middle of the 18th century. At that time, physicians were paid for the medication they dispensed and not for the services they provided. It was professionally and legally not appropriate for physicians to demand payment for services, because treating patients was a humanitarian act. However, payment for medication was appropriate, because physicians must earn their living and the ingredients had to be purchased (Fuse, 1979). At that time, prescribing and dispensing were intricately linked; physicians were also referred to as "kusushi" (apothecaries). Dispensing continued to be a major source of the physicians' income until well after the end of the Second World War. At its peak in 1980, payment for pharmaceuticals, which would include the profits providers made from dispensing, composed 38.7% of national medical expenditures (Kenkou Hoken Kumiai Rengoukai, 2017).

The development of hospitals was also different. In Western countries, hospitals began as charity institutions for the poor. In Japan, hospitals were built by the government from the latter half of the 19th century as part of the general policy to Westernize the country. The objectives lay in the following: treating soldiers, educating medical students, and isolating patients who had communicable diseases. However, these government hospitals remained few. Most hospitals were built by physicians adjacent to their clinics for patients who were able to pay. As a result, there was no clear distinction between clinics and hospitals. In general, hospitals did not provide nursing care. Patients were cared by their families, and nurses were trained to assist physicians. It was only after the reforms made by the occupying forces after Japan was defeated in World War II that patient care was legally defined as a nurse's responsibility (Ikegami, 2014).

Development of the Fee Schedule

When Social Health Insurance (SHI) was implemented in 1927, the government became the insurer for the Government-managed Health Insurance (GMHI), which covered manual workers employed in small companies with less than 300 employees. At that time, the services were overwhelmingly delivered by private practitioners who were paid on a fee-for-service basis for the services and the medications they dispensed. Thus, in the GMHI's Fee Schedule, the basic unit ("point") was for a consultation that included one day's dosage of a basic pharmaceutical (such as bicarbonate of soda) dispensed by the physician (Aoyagi, 1996). Other fees were set

relative to this basic unit and expressed in points. The Fee Schedule was very simple and is said to have been designed overnight by the JMA President (Fuse, 1979).

The conversion rate of the "point" to yen was negotiated between the JMA President and the Director of the Social Affairs Bureau in the Ministry of Interior, who was responsible for the GMHI. The rate was set below the customary level. The JMA agreed to this rate, partly because GMHI-enrolled patients composed only a fraction of their patients (other patients would continue to pay in full) and partly because physicians would no long be at risk of not being paid. Funding came from premiums, half of which were levied on GMHI enrollees and half on their employers, plus another 10% from general revenues. This subsidy was justified because SHI would make workers more productive, and thus increase the nation's wealth (Shimazaki, 2011). Averting the risk of a socialist revolution was also an objective. The conversion rate varied in each prefecture: if the physicians in the prefecture billed more "points" per GMHI enrollee than the national average, then the conversion rate would be lower.

The GMHI Fee Schedule was adopted by Society-managed Health Insurance (SMHI) plans, which enrolled employees of large companies, and the Mutual Aid Associations (MAA) plans for public-sector employees in 1943, thus unifying the fee schedules of all employment-based health insurance (EHI) plans. In that year, the conversion factor of the "point" to yen became fixed irrespective of the volume of services. The war-time inflation and general shortage of supplies had made it difficult to set the conversion rate based on the volume of services delivered.

For those not formally employed, Community-based Health Insurance (CHI) plans were legislated in 1938. CHI was focused on improving the health of the rural population, which composed more than half of the total population at that time. The army needed to draft more men because of the escalating war with China. Strong pressure was put on municipalities to establish CHI plans. To pay providers, each plan could set its own way of payment and individually contract with providers. In rural areas, the facility established and operated by the CHI was de facto the only provider of services. Few CHI plans contracted with providers outside of their prefecture.

In 1956, the government formally announced the implementation of Universal Health Coverage (UHC) in order to establish a welfare state. By that year, the country's GDP had recovered to the level before the Second World War had started. UHC was achieved not by restructuring the SHI system, but by expanding CHI. The CHI New Act legislated in 1958 had the following mandates:

1. All municipalities must establish a CHI plan for their residents
2. Everyone residing in the municipality not enrolled in an EHI plan must enroll in the municipality's CHI plan
3. All CHI plans must adopt the Fee Schedule of the EHI

The first mandate forced big cities, such as metropolitan Tokyo, to establish CHI plans. The second mandate forced everyone to enroll in a SHI plan. The two mandates led to the whole population becoming covered in 1961. The third mandate led to both services covered and payment to providers becoming the same for all SHI enrollees.[2] In order to finance the expansions of benefits, the national government increased its subsidies to CHI. Subsidies to GMHI had to be also increased because the income level of their enrollees who were employed in small companies was lower than that of SMHI enrollees. These subsidies from general revenues now compose a quarter of SHI expenditures, amounting to a tenth of the national government's general expenditures budget and twice that for defense (Ikegami et al, 2011). As a result, the revision of the Fee Schedule has become an integral part of the budgeting process, as will be explained later.

2 Those on public assistance are not enrolled in SHI. However, they are entitled to the same benefits, and the providers are paid according to the fees set in the Fee Schedule.

2
General structure of the payment system

Present health service delivery context

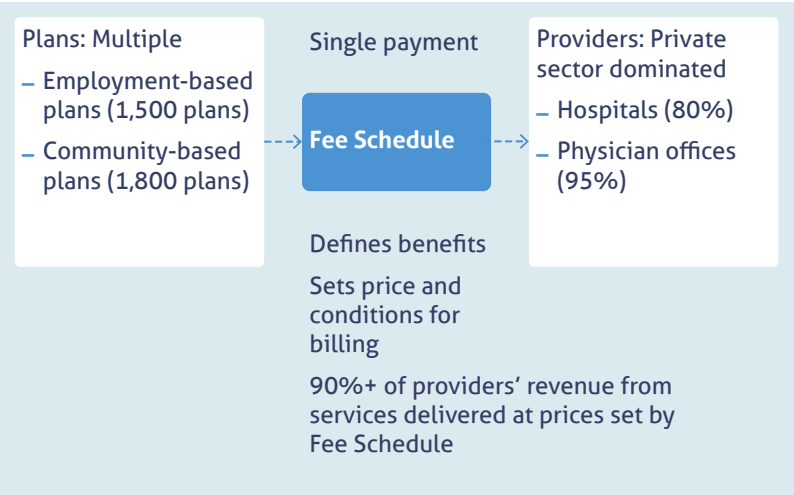
The number of physicians per 1,000 population is relatively low at 2.43 (OECD, 2018). Some 32% practice in clinics, and 63% in hospitals. Among clinics, the greater majority are proprietary-owned solo practices (MHLW, 2018a). Physicians based in clinics do not have access to hospital facilities, and the majority focuses on primary care services. Among hospitals, virtually all physicians are employed by the hospital, and their wages are generally set based on their seniority and do not reflect the revenue they generate for the hospital.

The number of hospital beds per 1,000 population is high at 13.1 (OECD, 2018). Of these beds, 57% are general beds for acute and post-acute care. Among hospitals, 69% have less than 200 beds (MHLW, 2018c), and 81% are in the private sector, which in many cases are owned by the physicians' family. In general, high-tech care tends to be provided by public or quasi-public sector (such as the Red Cross) hospitals, and post-acute care and chronic care by the private sector. Investor-owned for-profit organizations are not allowed to open hospitals. The hospital director must be a physician who usually continues to practice.

Key role of the Fee Schedule

Although the delivery system is fragmented, it is effectively controlled by the Fee Schedule. As Fig. 2 shows, the Fee Schedule simultaneously sets the benefits for enrollees of all SHI plans, and the service fees and the prices of pharmaceuticals and devices for virtually all providers in Japan. Both physician fees and hospital fees are listed in one Fee Schedule. In principle, payment is made to the facility and not to individual physicians. From this revenue, providers pay wages, purchase pharmaceuticals and other material, and retain profits so that investment can be made to meet future needs. This system may seem at odds with the fact that the Fee Schedule was originally designed to pay for the services of private practitioners. However, at that time, services were overwhelmingly delivered by solo-practice clinics, so that paying the clinic meant paying the physician.

Figure 2
Role of the Fee Schedule in Japan



Source: author.

The fees are officially set by the Ministry of Health, Labour and Welfare (MHLW) and are revised every two years based on the decisions made by the Central Social Insurance Medical Council of the MHLW.[3] This Council is composed of seven members from payers (SHI plans, business and labour groups), seven members from providers, and six members who represent public interests (academics), plus ten specialist members (representing nurses, pharmaceutical and device industries, etc.). However, council members do not vote. Indeed, the six members representing public interest are not allowed to speak unless asked by the chair (Morita, 2016). The Council exists to authorize negotiations that the MHLW officials in the Medical Affairs Division of the Health Insurance Bureau have made with provider organizations, such as the JMA, hospital associations, and specialist groups.

People in the Medical Affairs Division number 84 in total, including 20 physicians, 2 dentists, 2 pharmacists 2 nurses, and 12 career bureaucrats, with the rest being administrative staff. None have received formal training on the Fee Schedule, and except for the administrative staff, they are rotated every two to three years to different positions within the MHLW. However, they are responsible for all the work needed to revise and manage the Fee Schedule. The only exceptions are ad hoc studies contracted out to private companies on a tender basis.

3 Services not listed in the Fee Schedule include normal delivery (when SHI was first legislated, the enrollees were manual workers and male) and preventive services such as health screening. Services covered by accident insurance and other publicly funded programs use the fee schedule.

Restricting extra billing and balance billing

The percentage of providers' revenue not controlled by the Fee Schedule is about 10% on average from the data available (MHLW, 2017b).[4] The services that hospitals can set prices and directly charge patients are very limited. Extra billing, that is the billing of services and pharmaceuticals not listed in the Fee Schedule together with those listed, is mainly limited to new technology being developed by the hospital. Before being allowed to extra-bill the patient, the hospital must submit a request to the MHLW. If approved, the hospital conducts clinical trials to collect data on the service's efficacy and safety. If the results are positive, then the procedure would be approved and listed in the Fee Schedule, with its fee reduced from the amount that had previously been extra-billed. This was how heart transplants came to be listed in 2006 (Japan Organ Transplant Network, 2006).

Balance billing, that is billing the patient for the balance between the fee set by the Fee Schedule and the fee set by the hospital, is mainly limited to beds with better amenities. Hospitals may only balance bill if the bed meets amenity standards set by the MHLW and the proportion of the extra charge for beds in the hospital is less than 50% of the total for private sector hospitals and less than 30% for public hospitals. Note that physicians are not allowed to balance bill no matter how renowned they may be. "Gifts" (money packets) used to be given, but this is now much less prevalent.

Other than the above exceptions, if the patient wants to receive services or pharmaceuticals not covered by SHI, then he or she must pay for all costs out of pocket and not just the extra- or balance-billed amount. If a hospital was later found to have extra-billed or balance-billed patients for services not permitted, it must return the entire amount that they had billed the insurance plan for the services covered by SHI. Because of the benefit-in-kind principle, the bill cannot be divided into covered and uncovered services (except for those explicitly allowed). This strict interpretation has been attacked by pro-market economists as restricting the patient's choice (Ikegami, 2006). However, only minor concessions have been introduced, such as increasing the number of healthcare facilities that can extra bill non-approved pharmaceuticals mainly for cancer.

Because of these restrictions, complimentary private health insurance has not developed. The MHLW has maintained that all services and pharmaceuticals which have been evaluated for their efficacy and safety will be listed in the Fee Schedule. Substitution private health insurance plans do not exist in Japan because all residents in Japan are legally required to enroll in SHI plans. Thus, although 88.5% of households are enrolled in private health insurance plans (Seimei Hoken Bunka

4 The revenue from extra-charge beds and from preventive screening services are 1% each. 8% comes from non-health care activities. This ratio is 16% in local government hospitals because of subsidies, but is only 2% in private hospitals (earnings from investments). Disease-specific hospitals (such as for psychiatry) and hospitals that derive 2% or more of their revenue from LTC Insurance services are excluded from these data (MHLW, 2017b).

Center, 2018), they have not played a role in the setting or negotiating of prices in Japan. The greater majority offer cash benefits, irrespective of the out-of-pocket amount, for the days hospitalized or the visits made, or as a lump sum, when diagnosed and treated for cancer or other serious diseases.

The basis of these strict rules on extra billing and balance billing lies in the fact that SHI benefits are in kind (services) and not in cash (as would be the case for an indemnity insurance that reimburses part of the costs incurred by the enrollee). This principle dates to days when SHI was first implemented. At that time, there were no coinsurance, and the SHI plan paid providers directly for the services delivered to their enrollees. This benefit-in-kind principle has been maintained even after coinsurance was levied on dependents when they were covered in 1938 and later in 1984, when coinsurance came to be levied on the employees themselves.

Nationally uniform fees

The same fee is set for the same service throughout Japan. As previously explained, when the Fee Schedule was first introduced, the conversion rate of the points to yen differed according to the volume of services that had been delivered in each prefecture. However, the conversion rate became fixed in 1943 regardless of the volume. At that time, there were three rates reflecting urban-rural differences in the cost of living. This was reduced to two rates in 1948 and became one rate in 1963.

The fact that fees are nationally uniform may have contributed to a more equitable distribution of physicians and nurses. All facilities receive the same fee for delivering the same service. Out of this revenue, big city hospitals can recruit physicians at relatively low wages because they offer non-monetary rewards, such as allowing them to focus on their sub-specialty and to use high-tech equipment. However, they must pay nurses higher wages because the cost of living is higher. In rural hospitals, the reverse is true: there are higher wages for physicians and lower wages for nurses. Supporting data are available from public hospitals. In hospitals established by big cities (over 700 000 inhabitants), the annual wages were 13.6 million yen for physicians and 5.1 million yen for nurses. In hospitals that are established by towns and villages (less than 30 000 inhabitants), the wages were 17.9 million yen for physicians and 4.6 million yen for nurses (MIAC, 2017). Although there are no data for private sector hospitals, the differences are likely to be greater because their wages tend to be less seniority based.

The extent to which paying the same fee for the same service item has contributed to a more equitable geographical distribution of physicians and nurses is difficult to evaluate. However, as a method, it is simpler than setting fees to reflect the cost of living and then paying a bonus to physicians who work in rural hospitals. Currently, the age-adjusted per capita

medical expenditures differ by a quarter between the highest and lowest of the 47 prefectures (MHLW, 2017a).

Defining items and the conditions of billing

Providers are basically paid on a fee-for-service basis for the service items they have delivered. Each item is precisely defined. As an example, the fees for physician consultations are divided into the fee for an "initial" visit and a fee for a "repeat" visit. The fee for the former is four times that of the latter, reflecting the fact that the time and effort required for an initial consultation are much greater than that required for a repeat consultation. In the Fee Schedule, an "initial visit" is defined as a visit made 29 days or more from the previous visit and without having the physician ask the patient to make the next visit 29 days or more after the previous visit.

Conditions of billing effectively control the volume of each item. They have been set to contain costs and assure quality. For example, to bill for rehabilitation therapy, the hospital must employ more than the defined minimum number of experienced physicians and therapists, have a therapy room with a floor space of 150 m^2 or more, and so forth. To target resources and contain costs, patients must have had a stroke within 180 days, an injury within 150 days, and so forth.[5] For positron emission tomography (PET) scans, the hospital must meet facility standards such as having an experienced radiologist on site, and patient standards such as those who have a confirmed diagnosis of cancer (so that it cannot be billed for screening purposes). To bill for the bonus of managing the dietary needs of inpatients, the physician and staff must have attended designated seminars.

The most complex conditions have been set for basic hospitalization fees. The general rule has been higher fees for higher nurse staffing levels. This was introduced in 1951 as an incentive for hospitals to hire more nurses and not depend on the family for the care of the patient. Since then, the Japan Nursing Association (JNA) has lobbied to increase the staffing ratio to improve labour conditions and enhance their professional status. In addition to the staffing level, night duty must be less than 72 hours per month, and the proportion of registered nurses (as opposed to licensed practical nurses) in the hospital must be 70% or more. Work intensity was initially only measured by the hospital's average length of stay: 18 days or less for the billing of higher staffing levels. However, from 2006, more specific conditions, such as the proportion of patients in the unit who have had a major surgery or have cognitive problems and so forth have been added and have since been made more detailed.

5 The period is extended to patients who have designated diseases. Maintenance rehabilitation is provided by the long-term care insurance.

These definitions and conditions of billing have made the Fee Schedule very complex. In 1960, the manual had only about 100 pages. The 2018 version has more than 1700 pages in fine print, with about 4000 items and conditions of billing listed. In addition, there are separate manuals for the DPC (Diagnosis and Procedure Combination; the Japanese version of the Diagnosis-related groups [DRGs]) grouping book, for pharmaceuticals and devices.

Classification of the service items

Physician and hospital service items are classified as below. In each section, items are identified by a three- or four-digit code. For many items, the patient's and facility's conditions for billing are set. Note that Section F, Prescribing and dispensing, and Section G, Injections, are independent sections despite the fact they compose only two pages each, reflecting their historical importance. Section C, Home care services, became a separate section in 1988 in recognition of its expanding role.

- A. Basic outpatient consultation and inpatient fees
- B. Specific outpatient consultation and inpatient fees
- C. Home care services
- D. Tests (laboratory and physiological)
- E. Imaging
- F. Prescribing and dispensing
- G. Injections
- H. Rehabilitation
- I. Psychiatric treatment
- J. Procedures (of eyes, ears, etc.)
- K. Surgical operations
- M. Anesthesia
- L. Radiation therapy
- M. Pathological diagnosis
- Medical procedures performed in LTCI health facilities for elders

Reflecting advances in technology

New items will be listed in the Fee Schedule if they are clinically distinct from existing ones and have significantly higher costs. For example, laparoscopic surgery was listed when it came to be widely used. Their fees are set 10% to 70% higher than that of an open surgery to compensate for the cost of the laparoscope and the skills needed to perform the procedure. The physicians' specialist associations submit a request, which is reviewed by the MHLW. If justified, the item will be listed in the Fee Schedule at the time of the biennial revision.

For equipment, fees are based more on their efficacy and less on costs. When magnetic resonance imaging (MRI) was first listed in 1982, its fee was set at twice that of computed tomography (CT) scans. At that time, the price of purchasing a MRI equipment was more than ten times that of purchasing a CT scanner (Hisashige, 1994). However, despite the low fee, providers purchased MRI equipment because it attracted more physicians and patients to the hospital. Meanwhile, the manufacturers gradually lowered the price of MRI equipment, which led to more hospitals purchasing the equipment. Thus, market forces have worked even when fees were regulated, and probably worked better because they were regulated.

Note that there is no government or quasi-government agency that is officially responsible for systematically conducting technology assessments. However, there is an expert committee within the MHLW that evaluates requests for new technology to be delivered as an extra-billed item, assesses efficacy based on the data collected, and recommends listing in the Fee Schedule. The division in charge of the Fee Schedule serves as the secretariat. Pharmaceuticals and devices are evaluated for efficacy and safety, but their costs are independently calculated. This will be described in the next section.

3
Pharmaceuticals and medical devices

Setting the price of a new pharmaceutical

Pharmaceutical companies must conduct clinical trials according to the guidelines set by the Pharmaceuticals and Medical Devices Agency (PMDA), an independent government agency. The PMDA evaluates the product's reliability based on ethical and scientific standards, and its efficacy and safety based on effectiveness standards. The Agency then gives a recommendation to the Pharmaceuticals Affairs and Food Safety Council of the MHLW to list the product in the National Formulary. When doing so, the dosage and the clinical conditions for on-label use will be specified in detail.

After approval, the Pharmaceutical Price Organization of the Central Social Insurance Medical Council evaluates the product's innovativeness, efficacy and safety, based on which it recommends the price. If the new product has a comparator, the price will be based on the comparator, with mark-ups for innovativeness, efficacy and safety. If there is no comparator, it is set by calculating the costs of research and development (R&D) and production based on the method set by the MHLW. The product's sales volume as estimated by the manufacturer will also be a key factor. If the volume is predicted to be small, then a high price will be set to allow the company to recover its R&D costs. The list prices in the USA, UK, Germany and France are also used to set the Fee Schedule price; the price must be set less than 1.25 times and more than 0.75 times the average price of these countries.

The government officially started to use pharmaco-economic analysis from 2019. The analysis is performed by the manufacturer, and the results are evaluated by the MHLW. The results will not be used to decide whether the product should be listed in the Fee Schedule but are used to provide additional data for setting the price. However, since the price of the new product is determined by many factors, the impact of the pharmaco-economic analysis results on the price are not clear. Parenthetically, the use of willingness-to-pay studies has been tabled because of the difficulties in conducting and interpreting the results (MHLW, 2018b).

Revising pharmaceutical prices

Pharmacies, hospitals and clinics purchase pharmaceuticals from wholesalers at prices which are usually lower than that set by the Fee Schedule.[6] They may retain the balance. To contain

6 For this reason, dispensing used to be done by hospitals and clinics. However, the profit margin has decreased, while the fee that physicians can bill if they dispense to a free-standing pharmacy has increased. The ratio of prescriptions dispensed within hospitals and clinics has declined to 30% of the outpatients' prescriptions (Federation of Social Insurance Associations). However, many of the pharmacies have strong ties with the hospitals and clinics that write the prescriptions. To discourage this trend, dispensing fees are reduced if the proportion of prescriptions from one hospital or clinic is more than 70% of the total number.

costs and the profits providers derive from dispensing pharmaceuticals, the MHLW conducts a survey of the wholesalers' and providers' books to calculate the volume weighted market price of every pharmaceutical product listed in the Fee Schedule. Based on these data, the MHLW revises the Fee Schedule price so that it will be just 2% higher than its volume weighted market price.[7] This rule applies for both brands and generics (generic products are "branded generic" in which each has its specific Fee Schedule price).

In addition to the above mechanism, prices will be reduced for new products that have sales greater than had been predicted by the manufacturer. The government justifies this reduction on the grounds that the manufacturer would be able to recoup the investments made for research and development from increased sales. For example, the price of OPDIVO was halved in 2017 following the expansion in the clinical conditions of its use.

Medical devices

Expenditures for devices are about one tenth that of pharmaceuticals. They have many characteristics in common, such as being produced by for-profit companies. However, the price of devices is set by the functional group into which the device is categorized. A new functional group will be set only when the new device differs significantly from an established group. For example, coronary stents are categorized only into a drug-eluding functional group and a non-drug-eluding functional group. There are now 212 functional groups for devices. The hospitals will only be reimbursed at the functional group price. The hospital might have to pay more than this price for a stent made by a manufacturer, but it is not allowed to balance bill the patient.

The price of a functional group is revised using basically the same method used for pharmaceuticals, but with the volume weighted market prices of the device by each manufacturer aggregated at the functional group level. For example, if the market price of a drug-eluding stent made by Manufacturer X having a 20% market share in volume is found to be 10% lower than its Fee Schedule functional group price, then the price of the functional group is reduced by 2%.

7 The method for revising pharmaceutical Fee Schedule prices has changed. When the survey-based method was first introduced in 1967, it was set at the 90th percentile from the lowest price; it became the 81st percentile in 1983 and, from 1987, was based on the volume-weighted average. The allowable margin (the "reasonable" zone concept) was introduced in 1994 in response to demands from the United States to make the transaction process more transparent as part of the Market Oriented Sector Selective negotiations. The "reasonable" zone was initially set at 15% but has since been gradually decreased to the present 2% from 2000.

4
Revising the Fee Schedule

Revisions of the Fee Schedule are made every two years for service fees and every year for the price of pharmaceuticals and devices (CAO, 2017).[8] The process is composed of the following three steps: first, setting the global revision rate; second, revising pharmaceutical and device prices, and third, revising service fees on an item-by-item basis. The global revision rate sets a de facto global budget for health expenditures within which the prices of pharmaceuticals and devices and the fees of service items are revised. Although the revisions may not be publicized in this order, and the global rate might have to be finely adjusted to reflect the terms negotiated in the second and third steps, the process is easier to understand if explained in the order below.

Setting the global revision rate

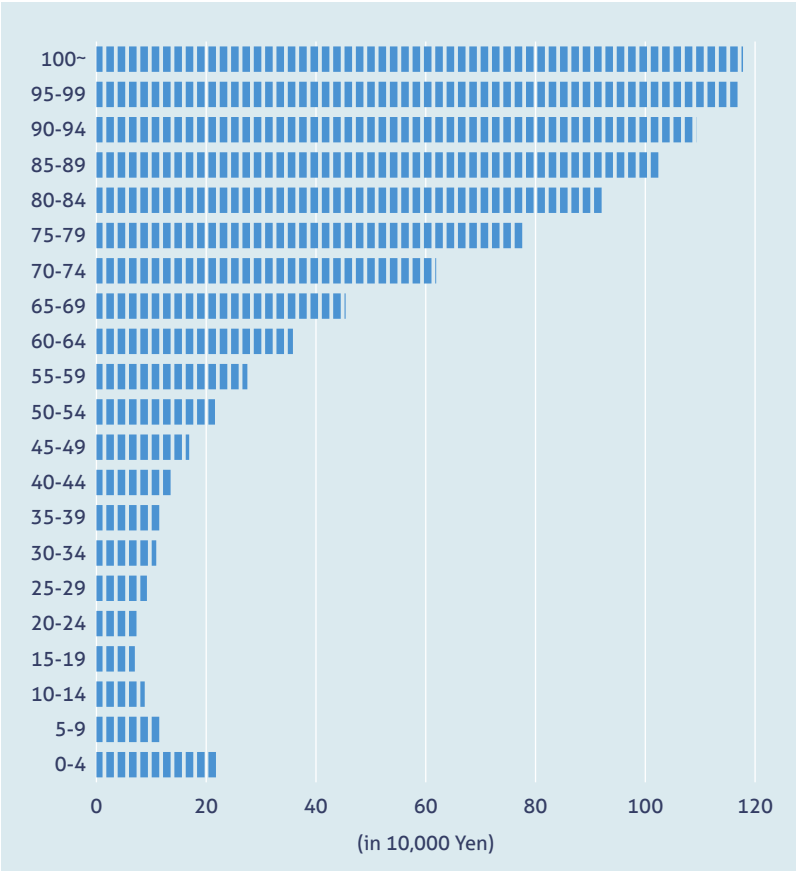
The first step is deciding the global revision rate, which sets a de facto global budget for all SHI and public expenditures in the next fiscal year. Next year's expenditures are determined by the equation below:

Next year's expenditures = This year's expenditures ∗ [1 + (the increase rate from population ageing + the increase rate from "other" factors) ± (global revision rate)]

The impact of population aging is calculated from changes in the population for each five-year age group. As Fig. 3 shows, expenditures vary greatly by age group. For example, the per capita expenditures of the 75-79 age group are ten times more than that of the 35-39 age group so that the increase in the 75-79 population will have much greater impact on expenditures than the decrease in the 35-39 population. It is assumed that per capita differences in health expenditures across age groups will remain the same.

8 Pharmaceutical and device prices will be revised annually from 2018 so that any decreases in market price are reflected more quickly in the Fee Schedule. The first revision in which they are revised independently from service fees will be made in 2019.

Figure 3. Per capita health care expenditures by five-year age group in Japan (2013)



Source: MHLW, 2018b.

Increases not due to aging (i.e., residuals) are referred to as "other factors." This is calculated by subtracting the annual rate of increase for aging from the increase rate of health expenditures, and then averaging the rates of the past three years. Population aging and "other factors" combined have increased health expenditures by about 2 to 3% every year. Thus, if the global revision were set at -4 to -6%, then healthcare expenditures will remain the same because this would cancel out the increases due to population aging and "other factors" in the next two years. This is why the Ministry of Finance (MOF) would like to set the global revision rate at -6%.[9] As has been noted, the national government's allocation to health care is one of the largest items in the budget, composing about one tenth of the total. This proportion has been relatively stable because the national government's contributions to SHI plans are statutory defined and the national budget has increased at about the same pace as that of SHI expenditures.

However, a -6% global revision rate would be vigorously opposed by providers. They would protest that a decrease of this magnitude would bankrupt them, thus denying access to patients. To arrive at a middle ground, the revision process begins with the two ministers of the MOF and MHLW, together

9 The greatest decrease so far was in 2006. The -3.16% revision rate was blamed for the closing of hospitals, resulting in newspaper headlines such as the "collapse of the healthcare system." Decreases of this magnitude would be politically difficult to make in the future.

with their top civil servants, discussing possible options. The final decision is made by the prime minister based on his evaluation of the political and economic situation. This decision will be made in mid-December annually, so that the national budget can be set before the country shuts down at the end of the calendar year (which will allow the new fiscal year to start smoothly from April).

In making this decision, the following two factors play key roles. One is the market survey of pharmaceutical prices. If the survey shows that the cumulative volume weighted market price of pharmaceuticals is 8% below the Fee Schedule price, then after allowing for the 2% margin, cumulative prices will be reduced by 6%. This 6% reduction will increase the global budget for medical services by 1.5%, because pharmaceuticals compose about one quarter of medical expenditures. In addition, there will be further savings by reducing the prices of new products that have sold more than the amount estimated by the manufacturer. These savings have been used to negate or soften the impact of decreases in the global revision rate. However, in the 2020 Fee Schedule revision, they would have less impact because pharmaceutical prices would already have been revised in 2019 to reflect the results of the 2019 market price survey.[10]

The second factor is data on the financial conditions of healthcare facilities from the Health Economic Survey (MHLW, 2017b). This survey is conducted in the year preceding the Fee Schedule revision, and the results should show that the facility expenditures are balanced by the facility revenues.[11] If the results show that the deficit has increased, it would be difficult for the MOF to argue for a negative revision rate. On the other hand, if conditions have improved, it will be difficult for the MHLW to argue for a positive revision rate. However, the results tend to differ by the type of provider. Thus, the Health Economic Survey tends to have more impact on how resources will be allocated among the various types of providers in the item-by-item revisions.

Setting item-by-item revisions

The global health care budget is appropriated to the medical, dental and dispensing services based on the relative share of each. About 80% of the total service budget is appropriated for medical services. Next, within the global budget, item-by-item revisions are made based on the equation below:

$$\textit{Global budget for medical services} = \textit{∑ (Fee of each item revised ↓↑)} * \textit{(Volume of each item increased or decreased by loosening or tightening the conditions of billing)}$$

10 Service fees will be revised together with pharmaceutical prices in October 2019, because of the introduction of the consumer tax. This tax is not levied on health care services so that fees and prices listed in the fee schedule must be increased to pay for the additional costs incurred by the providers.

11 With the exception of local government hospitals (as noted in reference 4), the proportion of subsidies is small. National hospitals have not received subsidies after they were reorganized into the National Hospital Organization in 2004 (Ikegami, 2014).

The left and right sides of the equation must be equal. That is, the cumulative effect of revising each item fee and its conditions of billing must be equal to the amount that has been set by the global rate and the increase rate from the "natural" increase and the savings that have been made from reducing pharmaceutical prices. The adjustments are made in a huge spreadsheet, in which item fees are individually revised so that the cumulative amount would be equal to the global budget. The volume of every item is available from the National Claims Database (NDB), which is compiled from the claims submitted by providers. Although the effect of tightening or loosening the conditions of billing on the volume cannot be predicted exactly, if the volume were to increase sharply, then the conditions of billing could be tightened in the next Fee Schedule revision or revised by ad hoc directorates from the MHLW if more immediate actions are needed.

Note that even small changes would have a big impact on costs if the volume is large (such as repeat consultations), while big changes would have little impact if the volume is small (such as complicated surgical procedures). Revisions could be targeted on specific items. For example, MRI fees have generally been decreased because their volume has increased rapidly, and because the price of purchasing a MRI equipment had been driven down as manufacturers competed to sell their products. The MHLW reported that increases in expenditures were blunted when fees were reduced by 30% in 2006 (MHLW, 2018c). Reductions of this magnitude had to be made to contain expenditures to the amount set by the global revision rate of -3.16%. Since then, fees have been increased for MRI equipment that have higher density in their imaging. These increases have been offset by reducing the fees of MRI equipment that have low density.

In general, fees have been revised to achieve the following policy objectives:

1. To contain expenditure increases by lowering the fees of items that have had rapid increases in volume and/or can be delivered at lower costs by providers.
2. To maintain appropriate profit levels across all hospital types so that they can continue to deliver services and make investments for future needs.
3. To provide incentives to physicians to deliver services in line with policy goals such as providing end-of-life care at the patient's home.

If providers do not deliver services in line with policy goals, then the conditions of billing could be rewritten in the next revision. Thus, item-by-item revisions could be regarded as a pay-for-performance (P4P) payment implemented at the national level.

Lobbying by provider organizations

The above does by no means suggest that providers have been passive in the Fee Schedule revisions. On the contrary, they have vigorously lobbied for an increase in the global revision rate. However, once the global revision rate is set, then the item-by-item revisions divide providers into those who gain and those who lose, which can facilitate negotiations for the government. Moreover, the JMA, which is the best organization among providers, has focused on increasing payment for primary care services, because their most powerful constituents are private practitioners. For example, the JMA lobbied for a new fee that physicians can bill for giving directions on improving lifestyle to patients with diabetes, hypertension or hyperlipidemia. This fee was introduced in the 2002 Fee Schedule revision. Billing of this item has been restricted to clinics and hospitals having less than 200 beds.

The Association of Surgical Specialties for Social Insurance succeeded in increasing surgical operation fees by 30% in the 2010 Fee Schedule revision. This revision was based on the results of their 2007 report (Gaihoren, 2007). The Association had conducted its first cost study in 1982. However, the increase owes much more to the change in the ruling party which brought in a surgeon as the vice minister. The Association's success prompted the Association of Internal Medicine Specialties for Social Insurance to conduct similar studies, but these have not had a similar impact.

The JNA has been lobbying for increases in basic hospitalization fees. As noted, to bill for higher basic hospitalization rates, the hospital must not only have to meet nurse staffing levels, but also the percentage of registered nurses must be 70% or more, and the night duty hours be less than 72 hours per month. When a higher level was introduced in the 2006 Fee Schedule revision, hospitals rushed to meet the required level because the increase in their revenue would more than offset the cost of hiring more registered nurses. However, in the 2018 revision, the JNA suffered a set-back when the higher fees were made more dependent on the patient's acuity level.

As the above examples illustrate, revisions of the Fee Schedule tend to be determined by politics. Perhaps for this reason, hospitals have not conducted cost studies that drill costs down to the level of each item. Instead, they have focused on the revenue and expenditure of clinical departments to decide which departments should be expanded or reduced. Studies have shown that the clinical departments that are more weighted to inpatient care, such as surgery, orthopedics and so forth tend to have bigger profit margins than those weighted to outpatient care such as dermatology (IHEP, 2008). This is because the Fee Schedule is structured to discourage hospitals, especially big hospitals, from delivering primary care services.

Note that the lobbying continues to the last minute so that the precise details of the conditions of billing may not be finalized

until the middle of March annually, just before the revision is implemented in April 1, when the new fiscal year begins. This means that software vendors of claims data must work day and night to reprogram their claims software. Hospital directors must estimate their revenue in the revised Fee Schedule, which may change the method of billing or how services are delivered.

Monitoring compliance to regulations

Compliance with the Fee Schedule regulations is first checked by the quasi-government organizations established in Japan's 47 prefectures. The main role of these organizations is to sort claims and bill the SHI plans for the services that have been delivered to their enrollees. However, they have a panel of renowned physicians in the community who review the claims and deny payment for items that are not appropriate. These physicians perform their task about five afternoons per month for which they are paid about US$ 1500. "Appropriateness" is evaluated by cross-checking the services and pharmaceuticals billed with the patient's diagnosis written in the claims form. If evaluated as being inappropriate, payment will be denied for that item. The amount denied composes only 0.3% of the total billed, but it has had a signal effect of alerting providers on what is permitted. Both payers (SHI plans) and providers can contest the decision. The panel will vote in favor of the contested cases in about one-third of the cases.

The second line check is by on-site "guidance", which is conducted by the regional office of the MHLW. "Guidance" is given to the facility every three to eight years: facilities that had more problems cited previously will be visited more frequently. The team, headed by a physician, comes with 20 to 30 claims forms that had been filed by the facility about six months before the visit. They will examine the medical records and closely question the physicians and other staff about the items billed. Should the documentation and responses be judged as being inadequate, then that item will be deemed as having been inappropriately billed. The facility will then be asked to retrospectively go through the claims filed in the past six months and return the amount that had been inappropriately billed. If the amount returned is judged to be too little, then the audit team will return and go through the records themselves.

The third line check is by "audit". Should the "guidance" reveal that the health care facility had intentionally and/or systematically submitted inappropriate claims, the "guidance" becomes an audit. The audit may lead to a temporary or permanent cancelling of the health facility's contract with SHI, which would effectively mean shutting down the facility. From 2005 to 2015, only 11 to 54 facilities each year have had their contracts cancelled, but the threat has served as an effective deterrent (Kenkou Hoken Kumiai Rengoukai, 2017).

5
Focused analysis

Primary care and specialist services

Primary care and specialist services are not differentiated in Japan. Most physicians have been trained as specialists. However, when they go into private practice, most focus on primary care because they will not be able to use hospital facilities to perform surgical operations and other complicated procedures. In contrast, hospital physicians can focus more on their specialties. However, many of their patients come without referral, and the physicians tend to continue treating their patients in the outpatient department after they have been discharged.

The government has long tried to functionally differentiate hospitals from clinics by the payment system. Fees have been set for physicians to write referrals (referred to as "information provision fees") from clinics to hospitals and from hospitals to clinics. However, the functions of hospitals, especially small ones, overlap with clinics. To take into account subtle differences reflecting the hospital's size, some outpatient service fees differ by the number of beds: 99 beds or less, 100 to 199, 200 to 399, and 400 and above. Incentives have also been introduced on the patients' side: if patients visit hospitals that have 400 or more beds without a referral, they must pay an additional amount.

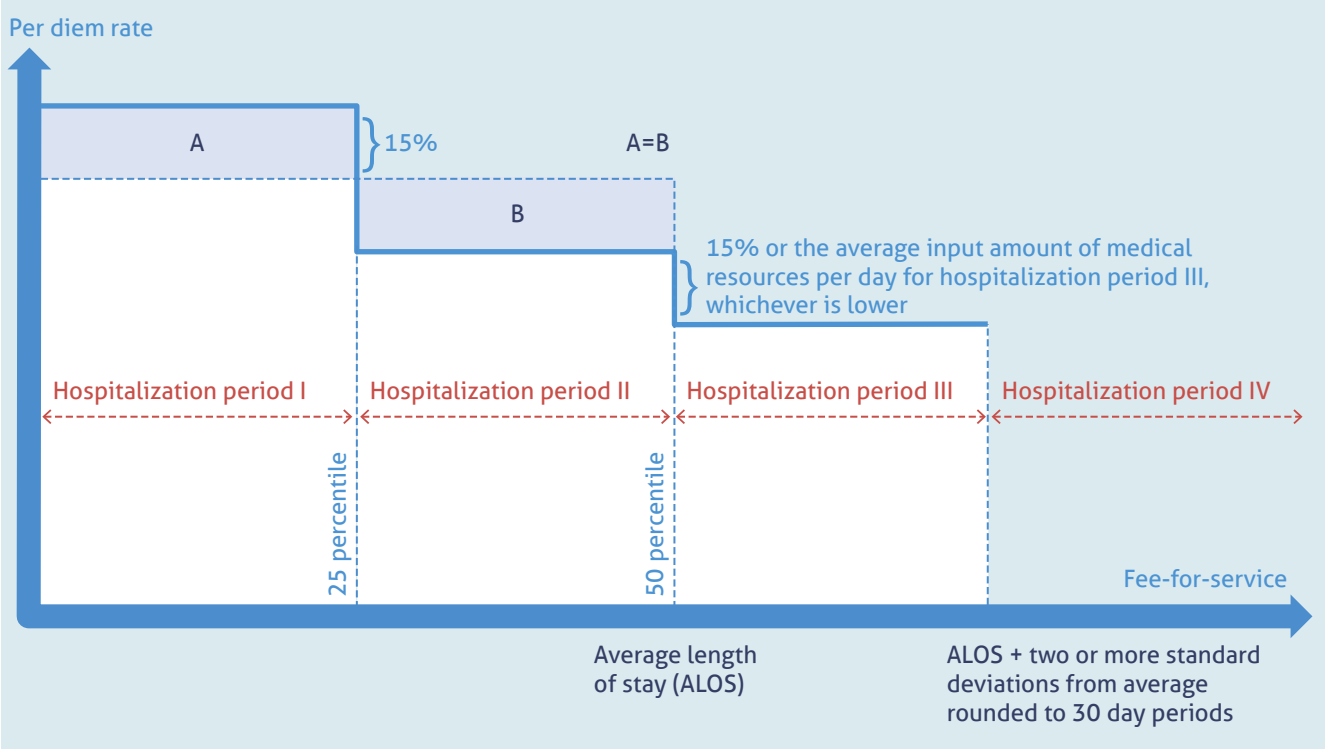
Acute inpatient care

A DRG type of payment, the DPC-PDPS (Diagnosis Procedure Combination – Per Diem Payment System) for the main 80 university hospitals and 2 national centres, was introduced in 2003.[12] However, surgical procedures, endoscopic examinations, rehabilitation therapy, devices, and pharmaceuticals given on the day of surgery are paid as fee-for-service. The inclusive part of the payment has the following characteristics.

Payment is on a per-diem basis and not on a per case basis. The per diem rate differs according to the four hospitalization periods which are specifically set for each DPC group. The periods are revised to reflect the lengths of stay as reported for each DPC group (Fig. 4).

12 Because service fees and pharmaceuticals are combined in DPC, the global revision rate is used for revising the DPC base rate.

Figure 4
Diagnosis procedure combination per diem rate for four periods of hospitalization in Japan



Note: DPC: Diagnosis Procedural Combination.
ALOS: Average Length of Stay.
Source: author.

The amount paid by the DPC is weighted by Hospital Specific Coefficients. For example, the "efficiency coefficient" rewards hospitals that have shorter lengths of stay after adjusting for the hospital's case-mix, and the "complexity coefficient" rewards hospitals that have more complex patients (higher volume weighted case-mix index).[13]

DPC fees were set to be budget neutral. If the hospital had continued to deliver the same services as it had under fee-for-service and the patient's length of stay had remained the same, then the hospital would receive the same amount of payment.[14] However, after adopting DPC, hospitals transferred services such as MRI to the outpatient department, where they could be billed as fee-for-service, and discharged patients earlier so that they would receive higher per-diem payment. This would increase hospital revenue, which was why the number of hospitals paid by DPC-PDPS has increased from 82 to 1,730, composing 54% of all hospital general beds in 2017 (MHLW, 2018c).

However, because patients have come to be discharged earlier, bed occupancy rates decreased, which may have led to a net decrease in hospital revenue. On the other hand, quality may have improved, because services have become more

13 Higher fees for hospitals with higher nurse staffing ratios are determined by another set of hospital functional coefficients.

14 When DPC was first introduced, there was a hospital-specific conversion coefficient that compensated for the difference between the fee-for-service payment and the DPC payment. This coefficient was gradually decreased from the 2012 Fee Schedule revision and dropped in the 2018 revision.

standardized when payment was standardized. Clinical pathways have come to be extensively adopted. Physicians no longer order the drip infusion of antibiotics every day while the patient is hospitalized. DPC has also led to the development of an extensive database of the hospital's case-mix, which can be used for regional health planning and hospital marketing purposes.

Chronic inpatient care

Hospitals began to provide chronic inpatient care when medical care for persons 70 years and older was made free (no copayment) in 1973. At that time, there was no other form of payment aside from fee-for-service, which led to over-medication and the excessive ordering of diagnostic tests in chronic care units. There were also not enough nurses because patients in chronic care hospitals faced long stays, that did not meet the conditions of billing that would allow chronic care hospitals to bill higher basic hospitalization fees. Care was delivered by private attendants who were hired by the patients to provide care 24/7. The presence of these attendants exacerbated crowding in the units: at that time, the floor space per patient was only 4.3 m^2 (this standard was set by the government in 1948, reflecting the housing conditions at that time).

In response, a new type of facility, the health facilities for elders (HFE), was established in 1986. Payment was a flat inclusive per diem amount. The HFE had to meet staffing levels, to have a floor space of more than 8 m^2 per bed and were forbidden to hire private attendants. Hospitals providing chronic care were encouraged to convert to HFE. However, because it was difficult to meet the minimum floor space standards, very few hospitals actually did so. For this reason, the government introduced a new form of payment for LTC hospitals in 1990, similar to the HFE, but with no floor space requirements. In the 1992 revision, a bonus payment was added if the hospital unit met the condition of "convalescent beds:" a floor space of more than 6.4 m^2 per bed, a dining room, and so forth. Because these standards were easier to comply than the standards for HFE, nearly all chronic care hospitals and units converted to convalescent beds so that by 2003, it became the de facto standard.

However, the flat per diem payment led to the perverse incentive of not admitting patients with high medical needs. To rectify this situation, case-mix-based payment was introduced in 2006 that was based on the patient's medical acuity and the activities in daily living (ADL) level (Ikegami, 2009). The fees for patients with the lowest medical acuity level were set below costs. The MHLW thought that hospitals would discharge these patients and close some of their chronic care units. However, a survey made one year after the introduction revealed that hospitals had not done so. They appear to have reclassified patients to higher medical acuity levels. Problems in the quality of care and data were also revealed: in one hospital, over 80%

of patients had been checked for urinary infection, which grouped the patients into a high medical acuity level. Some of these issues may have been rectified by on-site "guidance", but quality has not been systematically pursued by the MHLW.

Post-acute care and sub-acute care

Post-acute rehabilitation units were introduced in the 2000 Fee Schedule revision. The policy objective lay in shortening the length of stay in acute units by transferring the patients needing rehabilitation therapy to post-acute rehabilitation units, and in decreasing the need for chronic care beds by improving their functional status. Except for rehabilitation therapy, payment is bundled. The conditions of billing include the number of therapists per bed, the percentage of patients in the unit who have had a stroke or injury within the prescribed number of days, and for the patient to be admitted within 150 days of stroke or 60 days of accident. P4P was introduced in 2012. In the 2016 Fee Schedule revision, the performance indicator was revised. The unit's daily average improvement rate as measured by the patients' FIM (Functional Independence Measure) score became the indicator.

Sub-acute units were introduced in the 2004 Fee Schedule revision. The policy goal lay in creating a unit to which patients in the acute unit could be transferred and to which patients in the community not requiring the level of care delivered in the acute unit could be admitted. However, the latter function has not developed, because the bundled payment would put the hospital at risk of admitting patients who need more resources than would be paid by the Fee Schedule. Sub-acute units were renamed "comprehensive community care beds" in 2016, but with basically the same functions. In the 2018 Fee Schedule revision, to incentivize hospitals to admit patients directly from the community, higher fees were introduced if 10% or more of patients in these units had been admitted from the community and had not been transferred from acute units.[15]

Long-term care insurance services

LTC insurance (LTCI) was implemented in 2000 to meet the needs of the ageing society (Ikegami, 2007). It is compulsory that all people 40 years and over are enrolled. LTCI unified LTC services that had been provided by SHI, such as HFE, some hospital chronic care units, and visiting nurse services, such as those provided by social services, such as nursing homes, day care and home-helpers. Benefits are restricted to services (no cash benefits). The maximum cash equivalent amount of services that beneficiaries are entitled to is determined by the seven eligibility levels. The levels are based on functional capacity and range from about US$ 500 to US$ 3500 per month. Beneficiaries must pay a coinsurance, ranging from 10% to 30% based on the household income level.

15 Only hospitals that have less than 200 beds may bill these higher fees. Small hospitals had insisted sub-acute and post-acute care should be reserved for them and not for units in big hospitals.

The LTCI Fee Schedule has basically the same structure as that of the health insurance. The fees and conditions of billing have been revised to pursue policy goals and to respond to demands from providers. For example, a bonus payment for the home care agency to employ more experienced care workers was introduced in 2009. The policy objective lay in retaining these workers into the LTC workforce and improving the quality of care. To incentivize nursing homes and HFE to deliver end-of-life care within the facility and not transfer residents to hospitals, bonus payments were introduced in 2006. These bonuses and the conditions of billing have made the LTCI Fee Schedule as complex as that of health insurance. When first published in 2000, the schedule had only 100 pages, but the 2018 edition has 1000 pages.

However, the LTCI Fee Schedule differs from the health insurance Fee Schedule in three aspects. First, the rules restricting extra billing and balance billing are more relaxed because equity is less of an issue in LTC. Second, it is revised every three years, not two. Third, the conversion rates differ according to the eight levels in which each municipality is grouped: the rate for metropolitan Tokyo is highest at 11.4% above the base rate. Unlike healthcare, the higher wages of nurses and aides in urban settings cannot be compensated by the lower wages of physicians.

As LTCI services have developed, the boundary between institutional care and community care has become blurred. For example, special housing for elders that has a day care facility and a community care agency in the same building are de facto institutions. However, the following differences remain. First, in "housing", rent and food must be paid by the resident, but in an "institution", it would be mostly covered by LTCI if the resident is of low income and/or has few assets. Second, in an "institution", the facility is responsible for providing care 24/7, but, in "housing", the resident or the family is responsible. Thus, for those with behavioural problems requiring supervision, an "institution" may be the only option. For these reasons, there are long waiting lists to be admitted to nursing homes that do not balance-bill.

6
Possible lessons for other countries

As noted in the introduction, Japan's health care system appears to be functioning relatively efficiently, given the fact that the older persons as a share of the total population is the highest in the world, and the LTC system is well developed. These results may seem to be even more remarkable because they have been achieved within a basically fee-for-service form of payment. The key lies in the government controlling payment to all providers through the Fee Schedule. The following aspects should be noted.

First, all services and pharmaceuticals that have been evaluated as being effective are covered and listed in the Fee Schedule. Direct payment by patients in the form of extra billing and balance billing is strictly regulated. Without these regulations, patients, as consumers, would assume that they will get better services if they paid more. However, patients are not in a position to bargain with physicians on the price and quality of services.[16] Therefore, it could be said that policy-makers have been successful in managing the expectations of both the physician and the patient so that both parties are basically satisfied with the level of services that is covered by the publicly financed system.[17]

Second, fees have not been focused on the "costs" incurred by providers, but on the providers' revenue and expenditures. If providers respond to the incentives set by the Fee Schedule and manage themselves efficiently, physicians should be able earn comfortable incomes and hospitals could derive enough profits that would make it possible to invest in future needs. Revisions of the fees and the conditions of billing have been negotiated with the associations of physicians and hospitals based on this implicit understanding. The negotiations are structured, routinized, and in depth. Any unresolved issues could be postponed to the next revision after seeing how providers react.

While there is no perfect payment method, fee-for-service should not be dismissed as being intrinsically inflationary and reflecting only the providers' interests. Although fee-for-service would be difficult to introduce in countries that are dominated by big public hospitals, it should be noted that a DRG type of inclusive payment would also be difficult. Coding patients into clinically and economically homogenous groups requires the standardization of diagnosis, procedures, and recordings. There must be an appropriate monitoring system to minimize up-coding. There are also caveats in introducing capitation,

16 The situation would be the same for the payment made in free-standing pharmacies. In low- and middle-income countries where hospitals are financed by line-item budgets, physicians may instruct their patients to purchase pharmaceuticals from outside pharmacies because the hospital's supply is insufficient. This could develop into kickbacks from the pharmacies to the physicians. The same practice could expand to laboratory tests performed in free-standing facilities.

17 One area where balance billing could be allowed in the future is for services provided by renowned physicians, because their main value lies in their scarcity as positional goods. Differences in outcome would be very difficult to validate.

because without measuring and rewarding performance, it would be another form of paying fixed wages.

Thus, payment reform should start by developing a classification system of the services that are currently being delivered. Professional associations must be organized and co-opted into this process. This classification system would be the basis for establishing a payment system regardless of the method chosen, for negotiating with providers, and for conducting surveys. It would also facilitate the integration of the payment systems that are being currently used in the public and private sectors in the future.

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