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Abstract

In this study, the author analyzes the cost of medical equipment from a public finance perspective, using data from "Statistics of Production by Pharmaceutical Industry" and other sources. The analysis revealed the following two points. First, the size of the medical equipment market (as a percentage of GDP) has grown generally consistently from 0.37% in 2001 to 0.52% in 2018, an increase of 0.15 percentage points in about 17 years. This suggests that the cost of medical equipment in National Medical Care Expenditure may have grown slightly faster than the nominal GDP growth rate, although statistical issues must be kept in mind. Second, although CT and MRI are the most discussed high-cost medical devices, there are other medical devices that have a significant impact on public finances. There are 72 medical devices with a market size of 5 billion yen or more and an average growth rate of 1% or more. Medical devices with a market size of 100 billion yen or more are "sterile tubes and catheters for blood vessels," "other contact lenses," and "artificial joints, bones, and related devices," while the medical devices with a market size of 50 billion yen or more but less than 100 billion yen are "operating equipment and supplies, not elsewhere classified," "dental gold-silver-palladium alloy," "sense organ accessories" and "stents."

Keywords: medical equipment and systems, public finances, market size, average growth rate, medical materials

1. Issue Awareness

With the rapid development of digital technology, we are now faced with the challenge of how to integrate costs of innovative medical devices into National Health Insurance (NHI) and how to balance those costs with public finances.

One representative example of this is the case of the medical software "Join," which was insured as a medical device (and thus covered by NHI) in 2016, after the 2014 revision of the Pharmaceutical Affairs Law, which allowed software to be treated as a standalone medical device. This was the first case of insurance coverage for software, and it was a hot topic at the time. "Join," an application intended mainly for use in medical diagnosis, enables mobile devices to share image information about the human body provided by diagnostic medical devices (after a certain amount of processing).

That case is from more than five years ago; today, DX (Digital Transformation) in the healthcare field including telemedicine, prevention, and health is progressing further through the accumulation and bold utilization of medical and health data, leading to a growing possibility of greatly improving people's lives and health.

While it is clear that the development of innovative medical devices has the potential to create new markets and contribute to economic growth, employment, and tax revenues, financial constraints also exist. This is because the medical equipment market in Japan had grown to about 2.9 trillion yen in 2018, accounting for about 6.7% of the National Medical Care Expenditure of 43 trillion yen (FY2018). The market size expanded from 1.96 trillion yen in 2001 to 2.9 trillion yen in 2018, and may have grown at an average annual rate of 2.3% during this period.

Although not as large as the approximately 10-trillion-yen pharmaceutical market (which accounts for approximately 22% of National Medical Care Expenditure), as the medical equipment market is approximately 3 trillion yen, it is likely that discussion on balancing the costs of medical equipment with public finances will eventually intensify. NHI price revisions for drugs, previously made every other year, have been conducted annually since FY2021, out of concern for the sustainability of medical insurance finances. Medical devices (specified treatment materials) are also subject to official prices, which are currently revised based on biennial current market price surveys, but in the future, it is possible that medical devices will also be subject to annual price surveys and price revisions based on those surveys (as in the NHI drug price system).

For example, in the Future Directions for the Review of the Insured Medical Supplies and Materials System in Fiscal Year 2018 (Draft) (Central Social Insurance Medical Council (Chuikyo), February 8, 2017), the committee also requested necessary action on insured medical supplies and materials in line with the Basic Policy for Fundamental Reform of the Drug Pricing System (December 20, 2016).

In the midst of this severe financial situation, should it not be possible to encourage the creation of a new market by providing insurance coverage for innovative medical equipment through the establishment of an appropriate mechanism that will strike a balance with the financial situation?

The author believes that the clues lie in the establishment of (1) macro resource allocation commensurate with the growth rate and (2) proactive micro resource allocation for innovative medical devices. As a premise for the explanation, let us first briefly outline the current state of Japan's finances.

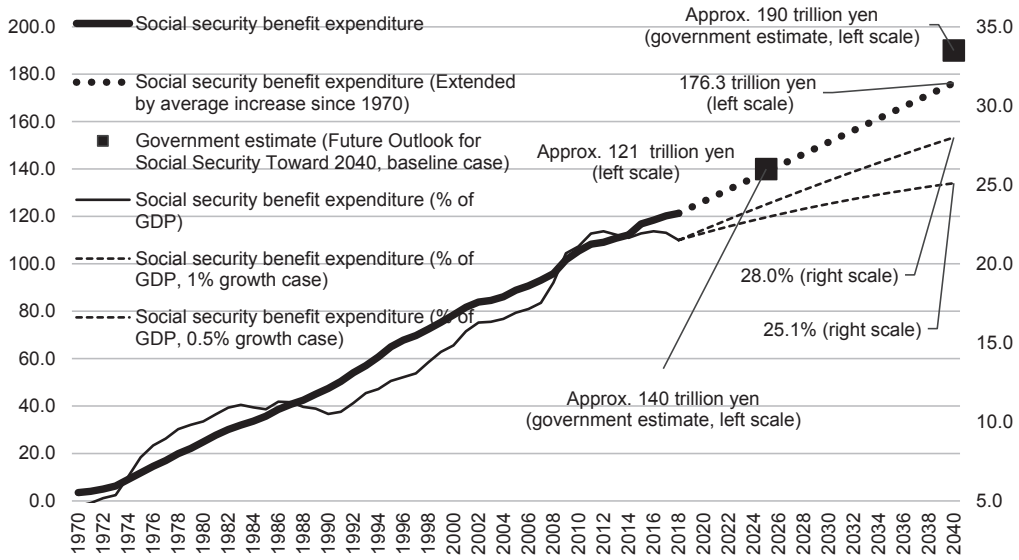
2. Current State of Japan's Finances

In the discussion on fiscal and social security reform, the government has positioned the *Future Outlook for Social Security Toward 2040 (Discussion Materials)* (in Japanese; hereinafter referred to as *"Future Outlook"*) published in May 2018 as a reference.

In the *Future Outlook* document, social security benefit expenditure is estimated according to two cases: high growth and low growth. In the low-growth baseline case, social security benefit expenditure is estimated to increase from 121.3 trillion yen (21.5% of GDP) in FY2018 to about 140 trillion yen (21.8% of GDP) in FY2025 and about 190 trillion yen (24% of GDP) in FY2040. With only 2.5 percentage points (= 24% - 21.5%) of GDP growth by FY2040, one opinion is that it is not necessary to rush reforms; however, the reality is that social security benefit expenditure in FY2019 (on a budgetary basis) increased by 2.4 trillion yen year-on-year to 123.7 trillion yen, or 22.1% of GDP, which is already higher than the projected figure for FY2025 (21.8%). (Note: FY2019 GDP is based on the Cabinet Office July 2019 estimate.)

The thick solid line (left scale) in Figure 1 shows the actual trend in social security benefit expenditure from FY1970 to FY2018, which increased at an average annual rate of about 2.5 trillion yen (equivalent to a 1% consumption tax rate). Although growth over the past few years has been slower than 2.5 trillion yen, the bold dotted line in Figure 1 shows the projected social security benefit expenditure up to FY2040, based on the assumption that this pace continues.

Figure 1: Trends and future projections of social security benefit expenditure (Left scale: trillion yen; right scale: % of GDP)



Source: Compiled by the author from "Financial Statistics of Social Security," National Institute of Population and Social Security Research, and others.

Of these, benefit expenditure in FY2025 would be approximately 138 trillion yen, which is close to the government's estimate, and the benefit expenditure in FY2040 would be 176.3 trillion yen, which is lower than the government's estimate. However, if, due to lower potential growth, the growth rate declines over the medium- to long-term, benefit expenditure as a percentage of GDP will rise. This is due to a certain degree of unpredictability in forecasting growth rates to calculate future nominal GDP, but even in the abovementioned baseline case, nominal GDP growth rate after FY2029 is projected to be 1.3%. An assumption of a growth rate of 1.3% is about three times higher than the average growth rate (0.39%) from FY1995 to FY2018.

Therefore, if we revise the growth rate assumption downward to 0.5% from FY2019 onward and estimate an average annual increase of 2.5 trillion yen in social security benefit expenditure (bold dotted line in Figure 1) as a percentage of GDP, the value in FY2040 would jump to 28%. It should be noted that under an assumption of a 1% growth rate, the same calculation results in a social security benefit expenditure (as a percentage of GDP) of 25.1% in FY2040, which is close to the government's estimate (24%) for a growth rate of 1.3%, but a 0.3 percentage point decline in the growth rate would result in a jump of about 1 percentage point in benefit expenditure as a percentage of GDP.

Since a 1% increase in the consumption tax rate would increase tax revenues by about 0.5% of GDP, if benefit expenditure (as a percentage of GDP) were to increase by 6.5 percentage points (= 28% - 21.5%) between FY2018 and FY2040, even excluding a reduction in the current budget deficit, financial resources equivalent to a consumption tax hike of about 13% would be necessary.

Theoretically, another way to finance the economy is the issuance of government bonds, but in the current severe fiscal situation, and with the continuing increase in government bonds in response to the Novel Coronavirus pandemic, whether this is really a sustainable means is questionable. As

Oguro (2020) and others have shown, the harsh reality of public finances can be easily confirmed by Domar's theorem in economics. Domar's theorem states that "even if an economy with a constant nominal GDP growth rate continues to run a budget deficit, if the budget deficit (as a percentage of GDP) is kept constant, the outstanding debt (as a percentage of GDP) will converge to a constant value." If we let the budget deficit (as a percentage of GDP) be q and the nominal GDP growth rate be n, the convergence value of the outstanding debt (as a percentage of GDP) = q / n is established.

In specific figures, in the baseline case of the Economic and Fiscal Projections for Medium to Long Term Analysis (July 2021), Cabinet Office, Government of Japan, the budget deficit (as a percentage of GDP) in FY2030 is given as 1.8%, and since the deficit will continue on an expanding trend thereafter, q = 1.8%. If n equals the average growth rate of 0.39% since FY1995, as already mentioned, the convergence value of outstanding debt (as a percentage of GDP) would be about 460% (= 1.8% / 0.39%), which is about 2.3 times the current outstanding debt level of 200%. Even assuming a growth rate of 0.5%, the budget deficit (as a percentage of GDP) would need to be reduced to about 1% in order to keep the outstanding debt (as a percentage of GDP) at approximately the same level as at present.

3. Definition of Medical Devices and Macro Analysis of Medical Device Costs

As mentioned above, Japan's public finances are in a difficult situation, but proceeding with social security reform without principles or basic philosophy and cutting the budget in the dark is problematic. As long as the budget grows in line with the medium- to long-term economic growth rate, incremental increase should be tolerated.

What is interesting in this regard is the difference between pressure to reform the pension budget and the healthcare and long-term care (LTC) budgets. As is well known, the 2004 pension reform introduced the "macro-economic slide" mechanism into the public pension system. Macro-economic slide is a mechanism that moderately adjusts the growth of pension benefits, taking into account the economic situation of society as well as the decline in the number of pensioners and the increase in average life expectancy, thereby stabilizing pension benefits as a percentage of GDP.

In fact, in the previously mentioned in *Future Outlook* (baseline case), pension benefit expenditure is shown to increase from 56.7 trillion yen to 73.2 trillion yen between FY2018 and FY2040, but pension benefit expenditure (as a percentage of GDP) remains roughly constant between 10.1% and 9.3%. The reason that the pension benefit expenditure (as a percentage of GDP) is stable is due to the existence of the macro-economic slide.

On the other hand, healthcare and LTC are different. For example, medical care benefit expenditure is said to increase from 39.2 trillion yen to 70.1 trillion yen between FY2018 and FY2040, which is similar in structure to pension benefit expenditure, but medical benefit expenditure (as a percentage of GDP) increases from 7% to 8.9%. LTC benefit expenditure (as a percentage of GDP) similarly increases, but pension benefit expenditure (as a percentage of GDP) remains unchanged.

Therefore, at present, the main targets of fiscal and social security reform are healthcare and LTC. Despite the fact that both pension benefit expenditure and healthcare and LTC benefit expenditure increase between FY2018 and FY2040, the introduction of the macro-economic slide stabilizes pension benefit expenditure (as a percentage of GDP) such that it is no longer a target for reform. Conversely, this means that as long as healthcare and LTC benefit expenditure grow in line with economic growth rates, the incremental rise in expenditure may be tolerated.

So how will expenditure on medical devices as a percentage of GDP change in the future? In order to understand this, it is first necessary to define the scope of medical devices. Legally, medical

devices are defined in Article 2 Paragraph 4 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "PMD Act"). In other words, the PMD Act defines the term "medical device" as "appliances or instruments, etc. which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure or functioning of the bodies of humans or animals (excluding regenerative medicine products), and which are specified by Cabinet Order."

Based on this definition, a wide range of medical devices exists, including CT, MRI, and X-ray equipment, as well as steel products for medical use such as scalpels and tweezers, and also including thermometers, pacemakers, and artificial heart valves. Furthermore, medical devices are classified into several categories according to (1) the effect on the human body, (2) the specialized knowledge and skills required to manage the device, and (3) the management of the calculation of reimbursement of medical fees.

Firstly, from the viewpoint of (1) the effect on the human body, there are three categories of medical devices: 1) Class IV: "specially-controlled medical device" that is highly invasive toward the patient and considered to pose a "significant potential risk to human life and health in the event of a side effect or malfunction occurring" and Class III: "relatively high risk to human life and health in the event of a side effect or malfunction occurring"; 2) Class II: "controlled medical device" considered to pose relatively low risk to human life and health in the event of a side effect or malfunction occurring; 3) Class I: "general medical device" considered to pose "little potential risk to human life and health in the event of a side effect or malfunction occurring." All medical devices fall into one of these three categories. For example, pacemakers are specially-controlled medical devices, MRIs are controlled medical devices, and scalpels and tweezers are general medical devices.

In addition, from the perspective of (2) the specialized knowledge and skills required to manage the device, there are classifications such as "controlled medical devices requiring special maintenance" (e.g., CT diagnostic imaging system), installation management medical equipment (e.g., medical devices for hyperbaric oxygen therapy or HBO)," and "specified medical devices" (e.g., artificial heart valves).

Furthermore, from the viewpoint of (3) the management of the calculation of reimbursement of medical care fees, there are the categories of A1 (comprehensive), A2 (specifically comprehensive), B (individual evaluation), C1 (new-function products), and C2 (new-function/technology products), which are the most important in relation to public finances. These classifications are based on the Chuikyo "Proposal on the Evaluation of Specified Treatment Materials" (September 24, 1993), after which the Listing System by Functional Category was introduced.

In general, reimbursement of medical fees is a way to set compensation for "medical services" and "goods used such as drugs and materials." However, unlike pharmaceuticals, for which the price is basically set for each item, there are some medical devices for which the material price is "set individually" and some for which it is "not set."

Of these, the latter (those for which the price of materials is not set individually) are Categories A1 (comprehensive) and A2 (specifically comprehensive), for which the reimbursement of medical fees is assessed and integrated with technical fees. Specifically, Category A1 (comprehensive) refers to low-cost and frequently used medical devices such as disposable syringes, gauze, sutures, and scalpels, while Category A2 (specifically comprehensive) refers to medical devices that have an integrated relationship with technical fees and are applied to specific technical fees such as surgery and examination. Medical devices such as laparoscopes, electrocardiographs, MRI, and ultrasound machines fall into this category.

On the other hand, the former (where the price of materials is individually set) is Category B (individual evaluation), which is called "specified treatment materials." This category cannot be

evaluated in Category A1 (comprehensive) or Category A2 (specifically comprehensive), and it applies to high-priced or large-market medical devices (e.g., pacemakers and balloon catheters).

Category C1 (new-function products) and Category C2 (new-function/technology products) relate to medical devices that cannot be evaluated under the existing functional categories or existing technical fees. Category C1 (new-function products) is used when there are existing technical fees, and Category C2 (new-function/technology products) is used when there are no existing technical fees. In other words, a medical device is classified as Category C1 (new-function products) if it cannot be evaluated under the existing functional categories but there is an existing technical fee, and Category C2 (new-function/technology products) if it cannot be evaluated under the existing functional categories and there is no existing technical fee. After the application is submitted, Chuikyo deliberates on the establishment and review of new functional categories. As in the case of pharmaceuticals, there are several methods for calculating material prices in the new functional categories. Representative methods include 1) the similar functional category comparison system (a method in which prices are calculated based on prices in similar functional categories), 2) the cost accounting system (a method in which costs are calculated by accumulating costs on an exceptional basis when there are no similar functional categories), and 3) the foreign reference price adjustment system.

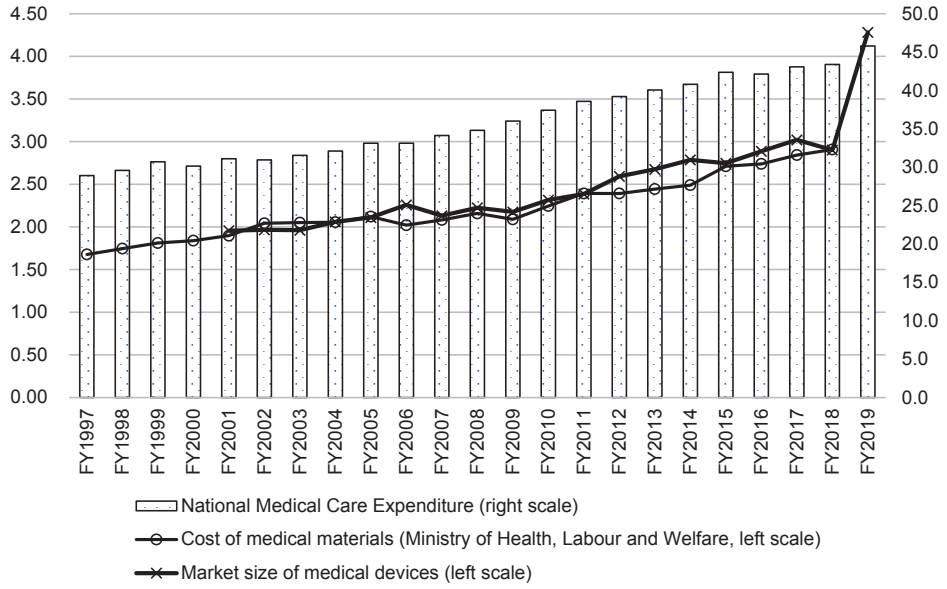
The above is the scope and definition of medical devices. The main reason that it is difficult to estimate the total amount accounted for by medical devices in NHI expenditure is that there are such categories as A1 (comprehensive) and A2 (specifically comprehensive) under the rules for calculating reimbursement of medical fees. Some of the medical devices have been integrated into the technical fee for the reimbursement of medical fees by inclusion or addition, which makes it impossible to grasp an overall picture of the medical device cost.

However, it is possible to comprehend certain things. For example, in the Structure of National Medical Care Expenditure in the *Annual Report on Health, Labour and Welfare* there is the item "medical materials (treatment, food service, etc.)" as the "medical fee structure of medical institutions." The figures in the *Annual Report on Health, Labour and Welfare* from FY1997 to FY2018 are processed, and the trends in costs of medical materials are plotted in Figure 2 below.

As shown in the figure, medical materials expanded from 1.68 trillion yen in FY1997 to 2.91 trillion yen in FY2018, an increase of about 73% or 1.23 trillion yen over 11 years, growing at an average annual rate of 111.8 billion yen. The growth of medical materials is larger than the growth of National Medical Care Expenditure, since National Medical Care Expenditure increased by about 50%, or 14.5 trillion yen, over 11 years, from 28.9 trillion yen in FY1997 to 43.4 trillion yen in FY2018.

However, attention should be paid to whether the cost of medical equipment is adequately captured in such medical materials. The relevant medical materials are estimated based on certain assumptions from "cost for medical supplies, material consumable equipment and supplies" and "food service supplies cost" in the Survey on Economic Conditions in Health Care, but there are also other expenses such as "medical device depreciation cost" and "rental fees for medical equipment."

Figure 2: Trends in cost of medical materials and market size of medical devices (unit: trillion yen)



Source: Compiled by the author from the *Annual Report on Health, Labour and Welfare*, Ministry of Health, Labour and Welfare, Japan; "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan, others.

Thus, the market size of medical devices in Japan was estimated by using "Statistics of Production by Pharmaceutical Industry" as shown in Figure 2. Since the statistics include data on values of domestic production, exports, and imports of medical devices, the size of the domestic medical device market can be calculated using the following formula.

Market size of medical devices = domestic production value - export value + import value

The values shown in Figure 2 were estimated by entering data from 2001 to 2019 from "Statistics of Production by Pharmaceutical Industry" into this formula. According to this data, the market size of medical devices was 1.96 trillion yen in 2001, which is close to the value of medical materials in 2001 (1.90 trillion yen). In addition, the market size of medical devices in 2018 is 2.90 trillion yen, which is also close to the value of medical materials in 2018 (2.91 trillion yen).

Therefore, the medical materials in the "medical fee structure of medical institutions" (*Annual Report on Health, Labour and Welfare*) may reflect the cost of medical devices relatively accurately, but it appears to require close scrutiny for the following reasons.

The first reason is that the value of the medical device market in 2019 increased rapidly compared to 2018. Using the latest data from "Statistics of Production by Pharmaceutical Industry," the market size of medical devices in 2019 is estimated to be 4.28 trillion yen, which is 1.38 trillion yen higher than the value in 2018 (2.90 trillion yen). However, this is strange, because, as already mentioned, costs of medical materials increased at an average annual rate of 111.8 billion yen from FY1997 to FY2018, but this is more than 10 times that increase.

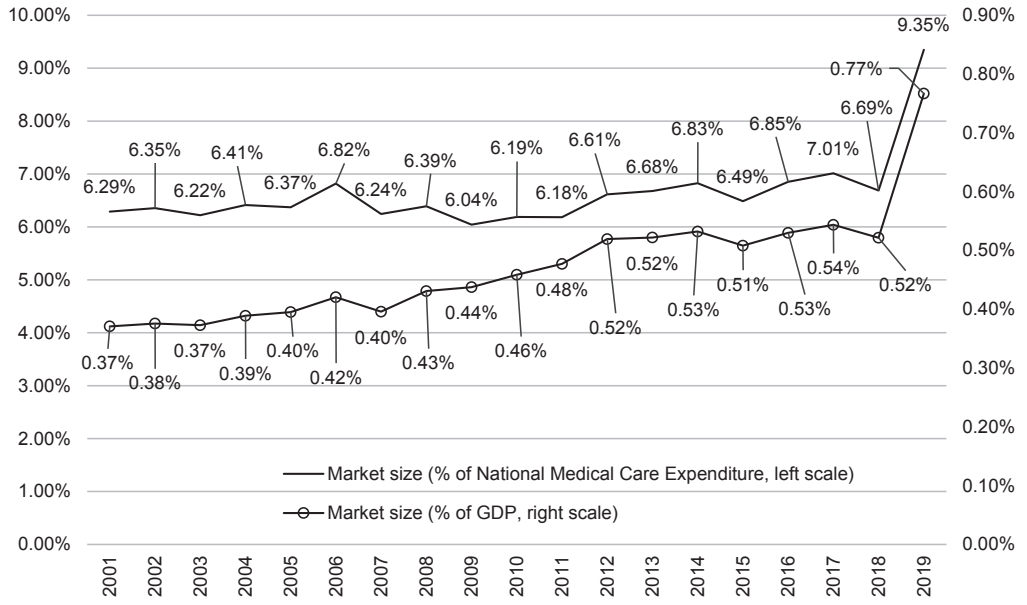
The second reason is that the survey methodology employed by "Statistics of Production by Pharmaceutical Industry" was fundamentally changed in January 2019, and "increases and decreases

have occurred from the figures of the previous year due to the improved collection rate, clarification of definitions, and other factors," which requires caution. If the values in 2019 relatively more accurately reflect the costs of medical devices than the market size of medical devices from 2001 to 2018, due to the change in the survey method, the values of medical materials in Figure 2 are not appropriate as a representation of the cost of medical devices. If the value for 2019 is more appropriate, it means that the value for medical materials may have underestimated the cost of medical devices.

Since it is difficult to make a judgment at this point, we will not pursue the issue any further, but will use "Statistics of Production by Pharmaceutical Industry" to analyze the market size of medical devices on a micro level as well as the ratio of the market size of medical devices to nominal GDP and National Medical Care Expenditure.

First, using the data on the market size of medical devices in Figure 2, Figure 3 shows the change in the market size of medical devices as a percentage of nominal GDP and National Medical Care Expenditure.

Figure 3: Trends in market size of medical devices (as a percentage of GDP) (unit: %)



Source: Compiled by the author using data from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare; System of National Accounts, Cabinet Office; and others.

As this Figure shows, the "market size of medical devices (as a percentage of National Medical Care Expenditure)" has been generally stable from 6.29% in 2001 to 6.69% in 2018, although it rose to 7.01% at one point (2017). The value at 9.35% in 2019 is higher than the value in 2018 (6.69%). Although this is a significant increase, it is difficult to assess the validity of the values at this time due to the statistical issues already mentioned.

However, the "market size of medical devices (as a percentage of GDP)" is different. It has generally grown consistently from 0.37% in 2001 to 0.52% in 2018, an increase of 0.15 percentage points in about 17 years, with an average annual increase rate of about 0.009 percentage points. This suggests that the costs of medical devices in the National Medical Care Expenditure may have

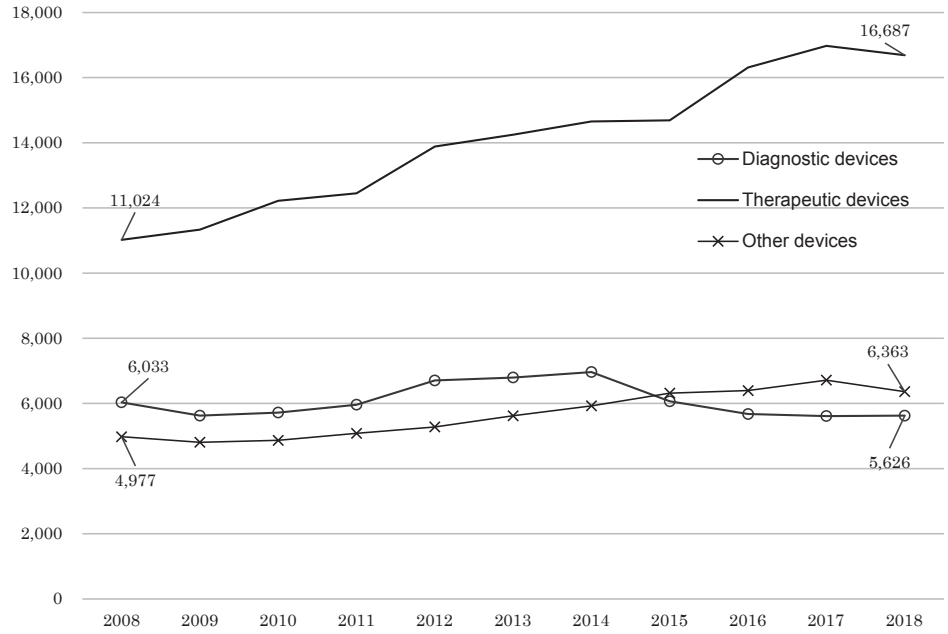
grown slightly faster than the nominal GDP growth rate, although it should be noted that there are some statistical problems, as already mentioned.

4. Factor Analysis of Trends in Medical Equipment Expenditure

Even though the cost of medical equipment in the National Medical Care Expenditure has been growing faster than the nominal GDP growth rate, it is not clear from macroscopic analysis what is causing this, and microscopic analysis is necessary to clarify the factors.

Next, to understand this factor in more detail, let us analyze the size of the medical equipment market on a micro level. One of the advantages of "Statistics of Production by Pharmaceutical Industry" data over the medical materials data is that it allows us to grasp the trends in the medical equipment market by application and product category. For example, as shown in Figure 4, the market size of medical equipment can be segmented by application and identified as "diagnostic devices," "therapeutic devices," and "other devices." In Figure 4, the category "diagnostic devices" consists of "diagnostic imaging systems (including CT and MRI)," "related devices and tools for diagnostic X-ray equipment" "measuring and monitoring systems for biophenomena," "in-vitro medical test equipment," and "clinical equipment and supplies." The category of "therapeutic devices" consists of "operating equipment and supplies," "artificial internal organ apparatuses and assistant devices," "therapeutic and surgical equipment," and "steel products for medical use." The category "other devices" consists of "dental equipment," "dental materials," "ophthalmic goods and related products," "surgical dressings and hygienic products," and "medical apparatuses for home use."

Figure 4: Trends in cost of diagnostic devices (unit: 100 million yen)

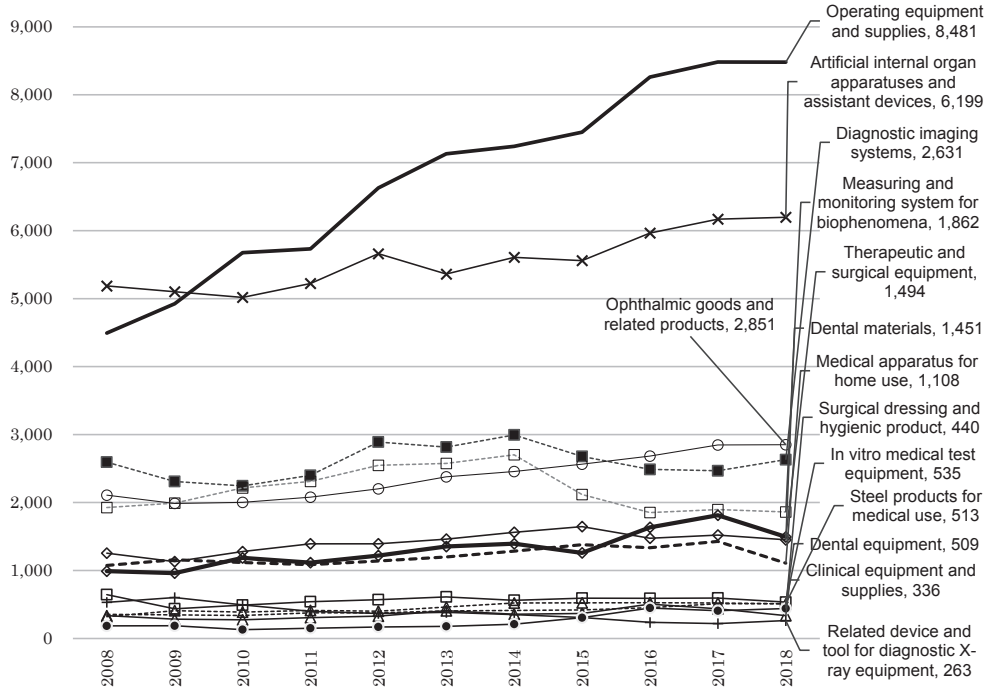


Source: Compiled by the author from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan.

From Figure 4, it can be seen that the largest expansion in market size has been in "therapeutic devices." The market size of diagnostic imaging systems (including CT and MRI) has decreased by 40.7 billion yen in about 10 years, from 603.3 billion yen in 2008 to 562.6 billion yen in 2018. On the other hand, the market size of "therapeutic devices" increased from 1,102.4 billion yen in 2008 to 1,668.7 billion yen in 2018, an increase of 566.3 billion yen in about 10 years, or an average annual increase of about 56.6 billion yen. In addition, "other devices" increased from 497.7 billion yen in 2008 to 636.3 billion yen in 2018, an increase of 138.6 billion yen in about 10 years or an increase of about 13.8 billion yen per year on average.

What, then, is the largest increase in medical devices by product category? To clarify this, Figure 5 was prepared without distinguishing between "therapeutic devices," "diagnostic devices," or "other devices."

Figure 5: Trends in the cost of medical equipment by product category (unit: 100 million yen)



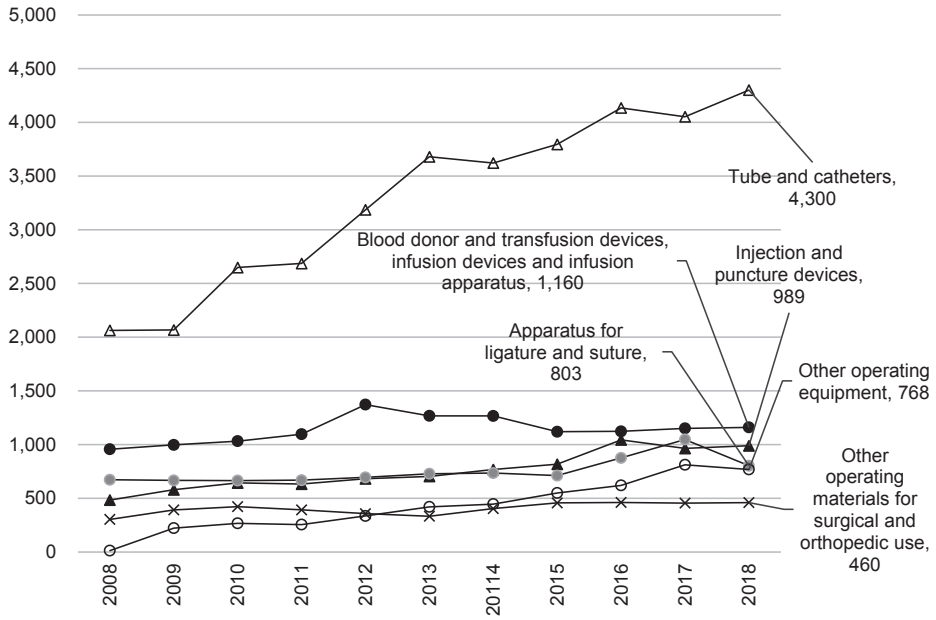
Source: Compiled by the author from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan.

As shown in Figure 5, among therapeutic devices, the market for "operating equipment and supplies" has shown the greatest expansion. In addition, there has been a large increase in the market for "artificial internal organ apparatuses and assist devices." Both "operating equipment and supplies" and "artificial internal organ apparatuses and assist devices" are therapeutic devices, and the market size of "operating equipment and supplies" has nearly doubled from 449.3 billion yen in 2008 to 848.1 billion yen in 2018, an increase of 398.8 billion yen over the past 10 years, or an average annual increase of about 39.9 billion yen. In addition, the market for "artificial internal organ apparatuses and assistant devices" has expanded by 101.2 billion yen over the past 10 years, from 518.7 billion yen in 2008 to 619.9 billion yen in 2018, an average annual growth rate of about 10.1 billion yen. The market for "diagnostic imaging systems" (including CT and MRI) grew only

3.6 billion yen over the past 10 years, from 259.5 billion yen in 2008 to 263.1 billion yen in 2018.

So, what item in operating equipment and supplies has exhibited the largest expansion in market size among the therapeutic devices? Figure 6 shows the trend in the market for operating equipment and supplies by category. This figure shows that the market for tubes and catheters has more than doubled from 206.4 billion yen in 2008 to 430.0 billion yen in 2018, an increase of 223.6 billion yen in about 10 years, or an average annual increase of 22.3 billion yen. As already mentioned, the average annual growth rate in the market for therapeutic devices from 2008 to 2018 was about 56.6 billion yen, which means that about half of the market increase was accounted for by tubes and catheters.

Figure 6: Trends in the market of operating equipment and supplies by category

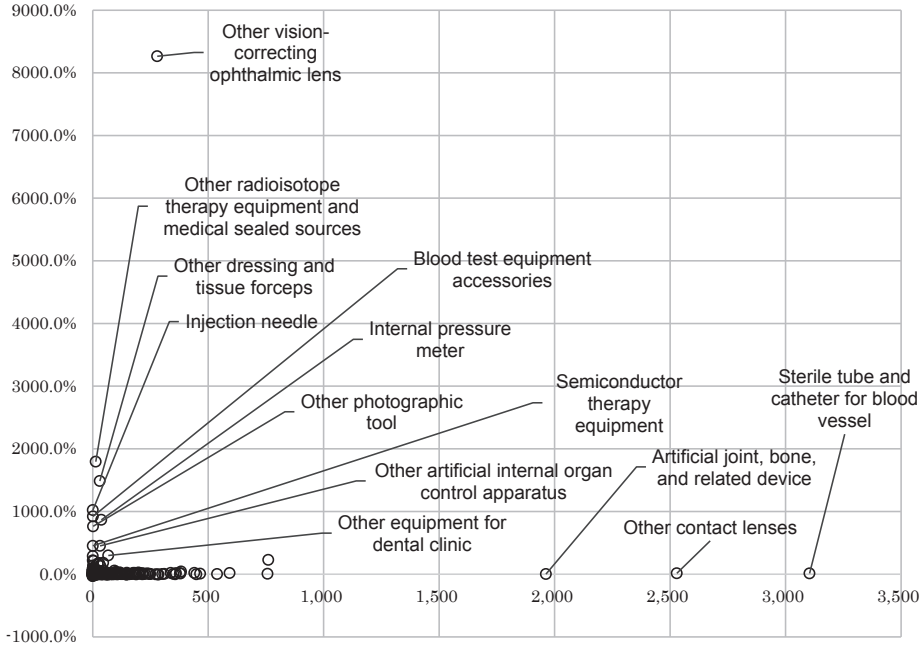


Source: Compiled by the author from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan.

Is there any way to grasp the whole picture of medical device costs, including the details of tubes and catheters? For this reason, Figure 7 was prepared by using all medical device data in "Statistics of Production by Pharmaceutical Industry."

The horizontal axis of this figure represents the market size of each medical device in 2018, the vertical axis represents the average growth rate of each market size from 2008 to 2018, and each plot point in the figure shows the positional relationship of 324 medical devices. For example, the plot point located on the rightmost side of the Figure represents "sterile tubes and catheters for blood vessels," the market size of which (in 2018) was 310.4 billion yen and the average growth rate of the market size (from 2008 to 2018) was 12.5%.

Figure 7: Market size and average growth rate of each medical device (unit: 100 million yen)



Source: Compiled by the author from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan.

In general, when the size of the medical device market and its average growth rate give an overall picture of medical device costs, there are four possible cases, as follows:

(1) Large market size and high average growth rate

(2) Large market size and low average growth rate

(3) Small market size and high average growth rate

(4) Small market size and low average growth rate

Of the above Cases (1) through (4), Case (1) is the one that should be watched most closely from the perspective of healthcare insurance finances, including evaluation of effectiveness, etc., while Case (4) is the least problematic. According to the "Economic and Fiscal Projections for Medium to Long Term Analysis" (July 21, 2021 edition), Cabinet Office of Japan, the nominal GDP growth rate until around FY2030 is roughly 1%. Therefore, for example, if the plot points in Figure 7 are classified according to whether the market size is more or less than 5 billion yen and whether the average growth rate is more or less than 1%, there are 72 products in the abovementioned Case (1), 31 products in Case (2), 150 products in Case (3), and 71 products in Case (4). Of the high-cost medical devices, CT and MRI in "diagnostic devices" are the most financially controversial. For example, the market size of whole-body X-ray CT scanner, which is included in the category of "diagnostic imaging systems" in Figure 5, is 44.9 billion yen with an average growth rate of -1.1% and belongs in Case (2). The market for superconducting MRI system, which is included in the category of "diagnostic imaging systems" in Figure 5, is 34.9 billion yen, with an average growth rate of 3.6%, and thus belongs in Case (1). In other words, CT and MRI, which are discussed in parallel, have different financial impacts, and it can be seen that MRI, which belongs in Case (1), may be more problematic than CT, which belongs in Case (2).

Let us now look at what medical devices other than MRI are included in Case (1), the most problematic category. Table 1 (a list of 70 out of the 72 products in Case (1)) was prepared to clarify this. The list shows that the medical devices with a market size of 100 billion yen or more are "sterile tubes and catheters for blood vessels," "other contact lenses," and artificial joints, bones, and related devices," while the medical devices with a market size of 50 billion yen or more but less than 100 billion yen are "operating equipment and supplies, not elsewhere classified," "dental gold-silver-palladium alloy," "sense organ accessories," and "stents."
(Note: It should be noted that some medical devices on this list are not covered by insurance, such as contact lenses and hearing aids.)

Table 1: Medical devices with a market size of 5 billion yen or more and an average growth rate of 1% or more

Medical device	Market size (2018, hundred million yen)	Average growth rate
Sterile tubes and catheters for blood vessels	3,104	12.5%
Other contact lenses	2,529	14.6%
Artificial joints, bones, and related devices	1,962	1.8%
Operating equipment and supplies, not elsewhere classified	760	227.1%
Dental gold-silver-palladium alloy	757	5.3%
Sense organ accessories	593	17.2%
Stents	538	1.5%
Infusion apparatuses	465	7.7%
Other surgical electrical devices and related equipment	440	19.8%
Other apparatuses for ligatures and sutures	383	42.3%
Cardiac valve prostheses	380	11.0%
Sterile injection needles	378	16.2%
Blood purifiers	361	16.7%
Superconducting MRI systems	349	3.6%
Surgical gloves and finger sacks	338	19.4%
Drug injectors	310	3.2%
Blood circuits	301	2.2%
Medical electrical equipment for endoscopes	248	2.5%
Sterile gastrointestinal tubes and catheters	248	2.8%
Sterile anesthesia needles	245	5.5%
Artificial blood vessels; vascular grafts	236	11.3%
Absorbable surgical sutures	227	3.7%
Ventilators	220	1.2%
Ultrasonic surgical equipment	215	15.7%
Sterile urinary tubes and catheters	204	4.6%
Diagnostic ultrasound imaging equipment	200	18.7%
Artificial heart-lung machines	198	26.4%
Sterile respiratory tubes and catheters	189	3.4%
Other tubes and catheters	184	14.1%
Ear-mounted hearing aids / Behind the ear type hearing aids	183	6.8%
Other operating materials for surgical and orthopedic use	182	20.1%
Digital radiographs	176	20.9%
First-aid adhesive plaster/tape	173	6.9%
Hemodialysis apparatuses	166	2.6%
Medical X-ray tubes and devices	160	1.5%
Sphygmomanometers, blood-pressure monitors	160	1.1%
Bone setting and surgical instruments	148	12.8%
Other equipment for peritoneal perfusions and related devices	148	22.1%

Dental units	139	1.3%
Other equipment for testing biophysical phenomena	125	8.6%
Electric therapy apparatuses for home use	122	3.6%
Active treatment devices for endoscopes	120	8.1%
Medical linear accelerators	120	2.2%
Puncture devices	117	29.1%
Laser surgical equipment and laser coagulators	116	2.0%
Diagnostic imaging systems not elsewhere classified	115	5.5%
Ophthalmic cameras	107	8.6%
Sterile blood access for blood purification	107	7.2%
Sterile nonwoven surgical products	103	14.1%
Denture adhesive	102	12.7%
Operating/surgical microscopes	99	33.5%
Medical non-woven gauze	99	10.6%
Other implantable devices and materials	97	28.5%
Clinical thermometers	96	5.9%
Sterile puncture instruments	95	8.2%
Other diagnostic nuclear medical devices and related equipment	94	56.4%
Single patient monitoring systems	85	2.6%
Visual function testing equipment	83	2.3%
Operating and treatment tables for clinical use	82	5.9%
Condoms	81	12.0%
Home magnetic therapy devices	73	4.9%
Massage tools	72	3.2%
Topical hemostatic agents	72	13.3%
Radiographic units	71	18.5%
Continuous electrolytic water makers	69	4.4%
Versatile data loggers and related equipment	66	18.9%
Artificial internal organ apparatuses and assists, not elsewhere classified	64	23.1%
Oxygen therapy equipment	63	15.6%
Dental drive units and hand pieces	59	9.2%
Dental X-ray machines	55	9.7%

Source: Compiled by the author from *Statistics of Production by Pharmaceutical Industry*

5. Summary and Future Issues

The following two points were revealed from the above analysis.

First of all, the market size of medical devices (as a percentage of GDP) has grown generally consistently from 0.37% in 2001 to 0.52% in 2018, an increase of 0.15 percentage points in about 17 years. Although there are statistical issues that need to be kept in mind, this suggests that, from a macro perspective, the cost of medical devices in National Medical Care Expenditure may have grown slightly faster than nominal GDP growth rate.

Secondly, from a micro perspective, there are 72 medical devices with a market size of 5 billion yen or more and an average growth rate of 1% or more. Medical devices with a market size of 100 billion yen or more are “sterile tubes and catheters for blood vessels,” “other contact lenses,” and “artificial joints, bones, and related devices,” while the medical devices with a market size of 50 billion yen or more but less than 100 billion yen are “operating equipment and supplies,” “dental gold-silver-palladium alloy,” “sense organ accessories,” and “stents.”

In the midst of the current severe financial situation, pressure for reform of healthcare and long-term care is increasing, and in the “Proposal on the Preparation of the Budget for FY2019” (November 20, 2018), the Fiscal System Council of the Ministry of Finance points out the following.

While the regional medical care initiative and the standard hospital bed system are mechanisms to regulate hospital beds to a certain extent, there is no system to manage the allocation of clinics and physicians, or of capital investment in high-cost medical equipment. Therefore, besides the system for hospital beds, a mechanism is necessary to correct the uneven distribution of medical resources, such as the number of clinics and physicians, and high-cost medical equipment, by clinical department and region, while controlling the increase in medical costs.

According to the FY2018 Budget Execution Audit (Ministry of Finance), there is a difference in the number of CT and MRI units per 100,000 population by prefecture. The prefectures with the highest number of CT and MRI have 21.8 (Tokushima Prefecture) and 10.2 (Kochi Prefecture), respectively, which is approximately twice the national average and triples the regional difference of the prefectures with the lowest number of CT and MRI. Furthermore, in comparison with OECD countries, the number of CT in all prefectures exceeds that of OECD countries, and the number of MRI in all prefectures exceeds that of OECD countries except the U.S. The higher the number of high-cost CT and MRI diagnostic imaging systems per 100,000 people, the lower the number of scans per device, while the fewer the number of imaging devices per 100,000 people, the higher the number of scans per unit. In regions with a high number of devices per population, there is a possibility that excessive capital investment is being made relative to demand, exerting pressure on the revenue of medical institutions. In light of these circumstances, from the viewpoint of efficient use of high-cost medical devices in the region, efforts should be made to optimize the placement of high-cost medical devices, including introduction of regulations that require prefectures and medical professionals to consult with each other when installing or renewing devices, while taking into account regional medical demand and the impact of the installation of high-cost medical devices on medical costs and the management of medical institutions.

As pointed out by the Fiscal System Council, it is clear that certain reforms are necessary, including appropriate allocation of high-cost medical devices (e.g., CT and MRI), in order to improve financial sustainability, but of these, only the "superconducting MRI system," is present on the list in Table 1.

In addition to the optimization of medical finances, the question of how to evaluate innovative medical devices from the perspective of promoting the medical device industry is also important.

In order to allocate financial resources in National Health Insurance (NHI) in a focused and efficient manner, the medical device pricing revision was conducted as a mechanism similar to the "new pharmaceuticals creation premium" ("premium to promote the development of new drugs and eliminate off-label use") in the NHI Drug Price Standards. In FY2020, a system called "reimbursement price adjustment premium" (added to the entire price calculated before the revision) was introduced to evaluate innovation in highly leading-edge medical devices. This is an incentive policy to encourage industrial promotion.

On the other hand, in order to meet the financial resource constraint, repricing based on market expansion is also introduced for medical materials, referring to the "repricing based on market expansion" mechanism of the NHI Drug Price Standards. Specifically, when the annual sales of specified treatment materials exceeds a certain multiple of the expected price ((1) the amount of annual sales exceeds 15 billion yen and is more than double the expected amount, or (2) the amount of annual sales exceeds 10 billion yen and is more than 10 times the expected amount), the price of the medical materials will be further reduced at the time of price revision. Basically, the maximum

reduction is 25%, and in the case of the similar functional category comparison system, the maximum reduction is 15%, which is a disincentive policy in place to restrain industrial promotion.

Balancing fiscal reconstruction and industrial development is not easy; however, in an effort to solve the problem of the coexistence of the "new pharmaceuticals creation premium" incentive policy and the "repricing based on market expansion" disincentive policy in the NHI Drug Price Standards, the Institute for New Era Strategy (INES) published a proposal to reform the drug pricing system on May 28, 2021. Entitled "A Reform Proposal for a New Drug Pricing System Consistent with Fiscal Sustainability — Centered around the assessment of priorities for drug benefits based on a philosophy of insurance benefits and macroeconomic indexing of drug costs —" the proposal has received a certain degree of praise from related industries. Policy recommendations similar to the INES proposal may be required for medical devices in order to promote the establishment of (1) macro resource allocation commensurate with economic growth and (2) proactive micro resource allocation for innovative medical devices. The study of the framework for this is a future issue.

In any case, it should be noted that the author does not intend that the budget for these medical devices be immediately cut. The Fiscal System Council of the Ministry of Finance calls for appropriate allocation of high-cost medical equipment (e.g., CT and MRI) in order to improve financial sustainability; however, the first step is to conduct a micro-level analysis of how the ratio of medical equipment costs related to GDP has changed and what has caused the increase in medical equipment costs. Following that analysis, in-depth discussion on proposals for reform should be conducted.

It is also important to consider medical expenses not as a cost but rather as an investment. We should not forget that the development of innovative medical equipment may create new markets and contribute to economic growth, employment, and tax revenue. What is most important is the perspective of how to construct a mechanism to promote the review of resource allocation (for new investment) under limited financial resources by making data as visual as possible, and referring to micro-analyses such as this one, when considering the balance between the cost of medical equipment and public finances.

N.B. In Japan, "Social Security benefit" expenditure includes expenditure for pensions, medical care, nursing/long-term care, and childcare.

References

Rebuilding the Japanese Economy, Oguro Kazumasa (2020), Nikkei Business Publications, Inc. (in Japanese)

"A New NHI Drug Price System Reform Proposal Consistent with Fiscal Sustainability: Based on the Insurance Benefit Philosophy, with a Focus on Prioritizing Pharmaceutical/Drug Benefits and Macroeconomic Slide of Pharmaceutical/Drug Costs" Institute for New Era Strategy (2021) (in Japanese)

"Future Outlook for Social Security with a View to 2040 (Materials for Discussion)", Cabinet Secretariat, Cabinet Office, Ministry of Finance, Ministry of Health, Labour and Welfare (2018) (in Japanese)

Statistics of Production by Pharmaceutical Industry, published annually by the Health Policy Bureau, Ministry of Health, Labour and Welfare of Japan, this report covers the status of production of drugs and medical devices, etc. English versions are available here: https://www.mhlw.go.jp/english/database/db-sp/index.html