ISSN 0911–1247

Journal of International Economic Studies

(NO.37)
March 2023

Special Issue

Industrial Economics of the Medical Device Industry
-Heading toward a Leading Japanese Industry-
Editor's Introduction — Takuma Sugahara — 1

Data Construction and Productivity Analysis on the
Medical Device Manufacturing Industry in Japan — Takayuki Ishikawa — 5

Comparison of Reimbursement Pricing Systems for
Medical Devices in Japan and Other Countries — Makoto Tamura and Takuma Sugahara — 23

Balancing Medical Equipment Costs with Public Finances — Kazumasa Oguro — 39

Challenges and Prospects in the Medical Device Industry
-Heading toward a Leading Japanese Industry- — Takuma Sugahara — 55

THE INSTITUTE OF COMPARATIVE ECONOMIC STUDIES
HOSEI UNIVERSITY

Tokyo, Japan

JOURNAL OF INTERNATIONAL ECONOMIC STUDIES

The Journal of International Economic Studies was first published in 1985 to serve members of Hosei University as a forum on international economic affairs and related fields. However, scholars from outside the University are also urged to submit papers. The Journal concentrates on discussions of international economic issues, particularly those related to the Japanese or other Asian economies.

All those who wish to contribute to this journal should consult the *Instructions for Contributors* printed on the inside of the back cover.

Copies of the journal are distributed free of charge to institutions serving the scholarly community. All communications should be addressed to the editorial secretary, the Institute of Comparative Economic Studies, Hosei University, 4342 Aihara-machi, Machida-shi, Tokyo 194–0298, Japan.

Journal of International Economic Studies (2023), No.37, 1–4

Industrial Economics of the Medical Device Industry -Heading toward a Leading Japanese Industry-

Editor's Introduction

Takuma Sugahara

We are pleased to present a special issue of *Journal of International Economic Studies* (JIES), entitled "Industrial Economics of the Medical Device Industry: Heading toward a Leading Japanese Industry. The spread of COVID-19 has truly caused enormous damage to the world, not only in terms of the loss of life and the scale of the impact on people's health, but also in terms of the length of the period. Due to the necessity to prevent infection, the movement and exchange of people around the world have been greatly restricted, and economic activities have been greatly affected.

It is also true that through the filter of this sudden disaster, social vulnerabilities that were not visible in conventional daily life were exposed. In Japan, many problems were discovered especially in the broadly defined medical care system, including the securing of vaccines and therapeutic drugs.

In addition to the problem of securing vaccines, necessary medicines, and the current outpatient and inpatient medical care provision system, the supply of medical devices and materials such as ventilators and extracorporeal membrane oxygenation (ECMO) also faced a severe situation. Still fresh in our minds are the severe situations that occurred, such as the shortage of gowns and masks to prevent infection. All in all, it can be said that these have raised our awareness of the problem of "how to secure the necessary medical care" in the event of a sudden change in the normal situation.

On the other hand, we must not overlook the fact that this "disaster filter" not only highlights urgent issues to be addressed, but also clarifies Japan's future mid- and long-term issues.

As the effects of vaccination become more widespread and social expectations for a specific drug against the new coronavirus are increasing, questions and challenges were shared about why the necessary vaccines and breakthrough therapeutic drugs could not be developed quickly in Japan. Similarly, with reports that ECMO will play an important role in saving the lives of critically severe patients, it seems that the social need for such advanced medical devices and expectations for further innovation have risen to an unprecedented level among the public.

In general, these are related to the awareness of the problem of "how to reshape the way medical care and related industries and systems should be changed" in response to changes in the social structure.

These two issues are a common problem awareness of this special issues, which deals with "medical equipment," which is indispensable in the provision of medical services. In other words, "How do we achieve a stable securing of the necessary medical equipment?" and "What are the conditions or institutions that are socially required to promote new innovative medical devices." These two issues are the "basso continuo" that runs through all papers in this special issues.

I wonder what you think about medical devices. If you have been admitted to a hospital, you may think of a large imaging device such as a CT or MRI. Blood pressure may be monitored if you are suffering from hypertension, or a stomach camera may be used if you have undergone endoscopy during a medical examination. These are relatively familiar medical devices, as there may be many

opportunities to see them. They are usually classified as "diagnostic" medical devices.

On the other hand, the number of people who recall scalpels, forceps, cardiac pacemakers, or catheters used by the physician during treatment may be somewhat small. As noted earlier, extracorporeal membrane oxygenation (ECMO) has been widely publicized due to the lifesaving treatment of critically ill patients with the new coronavirus. These are usually classified as "therapeutic" medical devices.

If you are told that everything from contact lenses, massage chairs, and emergency adhesive plasters are "medical devices," you may feel somewhat confused. However, by definition, these can also be classified as "Other" in medical devices, together with the above two categories.

As described above, there are three major categories of medical devices. The term "medical device" was originally defined, in accordance with the Pharmaceutical and Medical Devices Law, as "a device or device intended for use in the diagnosis, treatment or prevention of human or animal diseases, or for influencing the structure or function of the human or animal body." In recent years, software programs aimed at diagnosing, treating, and preventing diseases, as well as the above-mentioned "goods" have come to be considered as "medical devices" depending on the purpose of use and the degree of risk, and the scope of such programs has been expanding.

While the number of drugs listed on the NHI drug price list is 14,041 (Notification of the Official Gazette dated April 1, 2018), the number of medical devices based on the Pharmaceuticals and Medical Devices Law is more than 300,000 and the number of non-proprietary names is 4,000. The wide variety of usages and the large number of products make it difficult to comprehensively ascertain the actual situation in the medical device industry. In other words, this is the first factor that makes it difficult to comprehensively discuss the medical device industry.

Furthermore, the fact that many medical devices are handled within a complex public medical insurance system is a second factor that makes it even more difficult to clarify the structure of the industry itself. In Japan, under the universal health insurance system, the basic concept is that all necessary medical care is fundamentally covered by public insurance. Similar to drugs, medical devices are also subject to reimbursement by public insurance if their efficacy and safety are confirmed, and the need for diagnosis and treatment is met and is seen to be appropriate.

The treatment of reimbursement prices in the public insurance of medical devices is basically included in the technical fees for medical fees, and the prices are determined individually by functional category. In both frameworks, the revision of medical fees or the revision of material prices substantially affect transaction prices. The business depends greatly on changes in the medical treatment system and the revision of medical fees. In addition, a clinical trial notice or safety report is required before an application for approval of a device or determination of an insurance reimbursement price. Furthermore, a marketing business license for a medical device and a registration for a medical device manufacturing business are usually required in order to sell medical devices manufactured in Japan after approval. The systems and regulations related to medical devices thus cover almost all aspects of business activities. Without a precise understanding of the mechanisms and effects of these systems and regulations, it is impossible to approach the actual situation and structure of the medical device industry.

Considering this point, it must be said that grasping the actual situation of the medical device industry is extremely challenging compared to other industries. On the other hand, the importance of analytically and structurally clarifying the situation of the industry in question and deepening understanding of the ideal form of the industry in the future and the appropriate systems to lead to it is increasing rapidly. This can be said to be natural from the standpoint of the scale of the industry's responsibility to society and the increase in the relative importance of socioeconomic activities.

Japan is experiencing a increasing, an aging population, and a declining population. In order to

continue to grow, the three keywords of "resource conservation," "intelligence-intensive," and "high value-added" are key. The medical device industry meets all three of these conditions, and it is hoped that a wide range of manufacturing technologies that are globally competitive will be utilized. In this sense, the medical device industry can be regarded as an industry with a high potential to play a leading role in Japan in the future.

The contents of each paper are also briefly described below. The first paper presents a "Data Construction and Productivity Analysis on Medical Devices," compiling the basic statistical indices necessary for understanding the medical device industry in Japan, as well as ascertaining the actual situation of industries using these indices. The production price index for the medical device industry was prepared using existing official statistical data such as the Census of Manufacture, and the actual production value and added value of the medical device industry were clarified. While productivity improvement is a major challenge for Japan's industry as a whole, the level of labor productivity in the medical device industry itself is at a high level compared to other industries. However, it is suggested that the growth rate of total factor productivity, taking into account all input factors, has been sluggish in recent years compared to other industries. It is also emphasized that measures to improve total factor productivity must include active promotion of R&D, the efficiency of R&D, and an improvement in R&D return.

The second paper discusses the current state of the reimbursement pricing system for medical supplies and equipment in each country and its implications for Japan, targeting the five reference countries of Germany, France, the United Kingdom, the United States, and Australia, which are the price reference countries for the "Foreign Price Adjustment System" in determining reimbursement prices. Germany, the U.K. and the U.S. are fundamentally reimbursed under a lump sum payment system, whereas in other countries, reimbursement prices are set individually, as in Japan's specified medical supplies. In countries where lump sum payments are mainly implemented, there is a reimbursement price premium system for a certain period of time to compensate for the decline in profits from medical institutions due to price increases for improved products. In addition, there is a system to support the collection of clinical evidence. As a measure to support the appropriate introduction of new medical technology, case studies are presented that will serve as a reference for future discussions in Japan.

The third paper discusses the harmonization between reimbursement of medical devices and finances in the future. While the development of new medical devices will undoubtedly contribute to socioeconomic development through the creation of new markets and the restoration of human health, new technological innovations are also widely recognized as a major factor in the increase in medical costs. While the author's concern is to ensure sustainability under severe fiscal conditions, innovative medical devices are designed to create new markets while broadly incorporating them into insurance. The original estimates suggest from a macro perspective that the cost of medical equipment in national medical expenditures may have increased at a rate slightly higher than the nominal GDP growth rate, and the relationship between market size and growth rate for each product category is examined to "visualize" the state of cost growth from a micro perspective. It has been pointed out that the integration of macro and micro perspectives and consideration of systems that promote resource reallocation are necessary perspectives for the promotion of fiscal harmonization and innovation, as well as their social return.

In the fourth and final paper, we summarized the issues and outlook for further development and advancement of Japan's medical device industry as a leading industry in the future. The following issues were cited as points: research infrastructure development to promote innovation, examination of insurance reimbursement systems, institutional design to balance fiscal sustainability, the importance of international expansion to lead the domestic economy, and necessary responses for a

stable domestic supply.

Through these group of papers, we have attempted to ascertain the actual situation of the medical device industry from various perspectives. Despite the prospect of rapid development, there is still insufficient analysis of the industry compared to other industries. We emphasize that such efforts should continue with the understanding and cooperation of industry and policymakers, and will be delighted if this special issue can contribute to laying the groundwork for such analysis.

This special issue is part of the results of the International Comparative Study on the Issues and Future of Japan's Insurance Medical Materials System, a research project undertaken by the Hosei University Institute of Comparative Economics, led by the editor. I would like to express my sincere gratitude to our colleagues at the Faculty of Economics, Hosei University, who gave us the opportunity to produce this project and the staff at the Comparative Economics Research Institute, who have given us very generous support in managing the project.

The project participants and the authors of the papers in this special issue greatly encouraged me to publish this issue. I would like to once again express my deepest gratitude to them. The outcomes of this research project reflect the results of earnest discussions held at the Study Group on Future Medical Device Policy (chaired by Dr. Shuichi Tani, honorary professor at the International University of Health and Welfare) and the Study Group on Medical Devices and Socioeconomics (chaired by Dr. Shuzo Nishimura, professor emeritus at Kyoto University). These discussions were held regularly at the Institute of Medical Devices and Medical Devices, Japan, during the project period. I would like to take this opportunity to express my sincere gratitude to the study groups and their participants. In addition, the workshop attracted a large number of participants as observers, mainly from the policy departments of major medical device manufacturers both in Japan and overseas. We would also like to express our gratitude to the staff of the Medical Devices Center who set up and served as the secretariat for the workshop.

Finally, the project was financed by the Institute of Comparative Economics, Hosei University, and the Japan Society for the Promotion of Science ("Relationship between Economic Growth and Health Care Expenditures and Pharmaceutical Expenditures in Emerging Asian Countries and Japan" (FY 2019)). I would like to take this opportunity to express my deepest gratitude to the Institute of Comparative Economics, Hosei University, and the Japan Society for the Promotion of Science for their generous support.

Journal of International Economic Studies (2023), No.37, 5–21

Data Construction and Productivity Analysis on the Medical Device Manufacturing Industry in Japan*

Takayuki Ishikawa†

Abstract

Medical devices play an essential role in healthcare. However, statistics on the Japanese medical device industry are insufficient. This study provides statistics for Japan's medical device manufacturing industry from 1994 to 2016 using the Census of Manufacture (Ministry of Economy, Trade, and Industry). In addition, this study presents a fundamental analysis of industry, productivity analysis, and inter-industry comparison. As evaluated by labour productivity and total factor productivity, the medical device manufacturing industry (1) is research and development (R&D) intensive, (2) does not have sufficient investment in R&D, and (3) has low productivity. This study concludes that it is essential to improve the accuracy of data in the future and to publish data regularly.

Keywords: capital formation, medical device, productivity, R&D efficiency, statistics.

JEL classification: **D2, E2, I15.**

1. Introduction

Japan has faced problems in recent years with healthcare, including demographic changes, shortages of hospitals, financial stringencies, and COVID-19. In particular, the COVID-19 pandemic has been a significant challenge for modern medical technology and healthcare services in Japan.

The health services industry comprises three parts: hospitals, pharmaceuticals, and medical devices. Several studies have been conducted on hospitals and pharmaceuticals. However, there have been few economic analyses of the medical device industry. This seems to be due to the lack of adequate statistics on medical devices.

This study develops statistics for the medical device manufacturing industry. It also analyses the current state of the medical device industry based on these data.

The Census of Manufacture (Ministry of Economy, Trade, and Industry) was used to compile the statistical data. It covers the period 1994-2016 and is comparable to that of other industries.

* As this paper is a revised version of MDSI Research Paper No.32, I thank Professor Sugahara of Hosei University, Dr. Horie (GEM in Gakushuin University), Mr. Kakino (GEM in Gakushuin University), and Mr. Watanabe (Doctoral Student in Gakushuin University) for their helpful comments and advice on the early version of this paper. Additionally, I thank the Faculty of Economics in Rissho University for excellent suggestions and advice. This study is supported by Medical Device Strategy Institute.

† Assistant Professor of Faculty of Economics, Rissho University, 4-2-16, Osaki, Shinagawa-ku, Tokyo, 141-8602, Japan. E-mail: taka.ishikawa0405@gmail.com.

Comparing the medical device industry with other industries enables improved understanding of the development of the medical device industry and its successes relative to other industries.

Even before the COVID-19 pandemic, the Japanese economy was limited by prolonged stagnation. Japan also faces a declining birth rate and an aging and shrinking population. The contribution of past economic development has sustained the current social security system in Japan. This implies that it may be impossible to maintain the system if economic stagnation continues. Under these circumstances, evidence-based policymaking is vital for promoting the medical device industry, which is an essential part of the healthcare sector. It is therefore necessary to develop more accurate statistics and develop the analysis conducted in this study.

The main findings of this study are as follows. First, although the medical device manufacturing industry (MED-MI) is research and development (R&D) intensive, its R&D investment has stagnated. Second, labour productivity and total factor productivity (TFP) growth are stagnant. Third, R&D profitability and efficiency are stagnant.

This paper consists of five sections. Following this introduction, the second section explains the estimation method for an outline of the data. The third section shows the productivity analysis of MED-MI. The fourth section presents the relationship between TFP growth and R&D efficiency. The final section summarises our results and discusses future work. The statistical data are provided in the Appendix.

2. Data construction and statistical analysis

This section defines the medical device manufacturing industry (MED-MI) analysed in this study. The wholesale and retail sectors of the medical device industry in MED-MI[1] are excluded, since the focus here is on the manufacturing sector to measure performance compared with other industries and to estimate how many medical devices they provide. However, no definition is completely consistent with the concept of MED-MI. It is necessary to classify industries in order to measure them. MED-MI is thus defined as the industries indicated in the Census of Manufacture (Ministry of Economy, Trade, and Industry). Table 1 shows the sectors MED-MI[2] is constructed from.

Table 1. Definition Set of MED-MI

Industry classification in the Census of Manufacture			
1	Textile sanitary materials	7	X-ray equipment
2	Sanitary clothing	8	Medical instruments electronic equipment
3	Paper sanitary materials	9	Medical measuring instruments
4	Medical and sanitary rubber products	10	Medical instruments and apparatus
5	Scientific glass instruments	11	Microscopes and telescopes
6	Sanitary pottery	12	Ophthalmic goods, including frames

To measure real variables about sales and value added, we construct price indexes used by the

1 The definition of MED-MI differs from that used by Ministry of Health, Labour and Welfare (MOH). The definition used in this paper excludes the sector for sales of on medical devices, while MOH statistics includes the sales sector.

2 Of course, these industries also manufacturing some goods for medical services, but it is not possible to separate out and exclude these medical goods.

System of National Accounts (SNA, Cabinet Office). Suppose a nominal x_i for the ith industry and an SNA deflator for the ith industry is p_i, then, the real value R is:

$$R = \sum \frac{x_i}{p_i} \quad (1).$$

If the aggregate of the current value x_i is X, then there exists a price index for X equal to X/R. Figure 1 shows the price indices for output yield and value added of MED-MI. Figure 1 shows that the trend of these price indices is declining. In 1997 it was 1.143 in terms of value added, but in 2016, it had dropped to 0.955. This means that deflation occurred at an annual rate of 0.94%. This price decline means cheaper healthcare for patients. However, for MED-MI, revenue is declining because the prices of traditional products are falling.

Figure 2 shows the output, and Figure 3 shows the value added of MED-MI.

Figure 1. Price Indexes for Output and Value Added (2011=1)

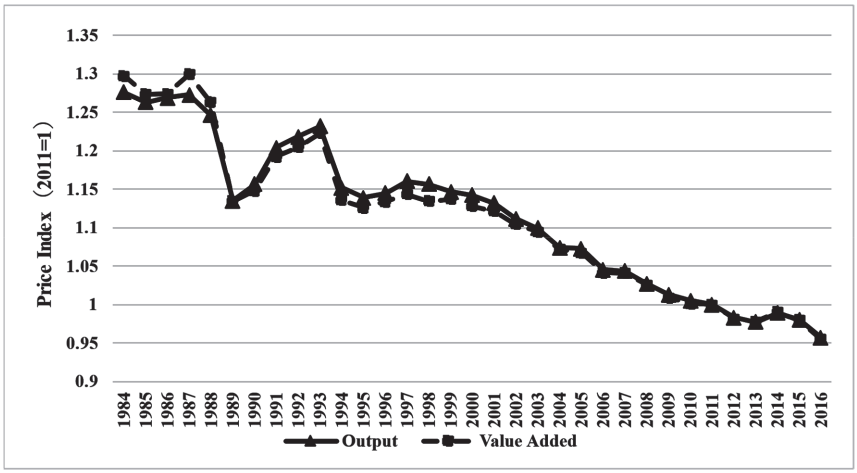


Figure 2. Output Value in MED-MI (Billion JPY)

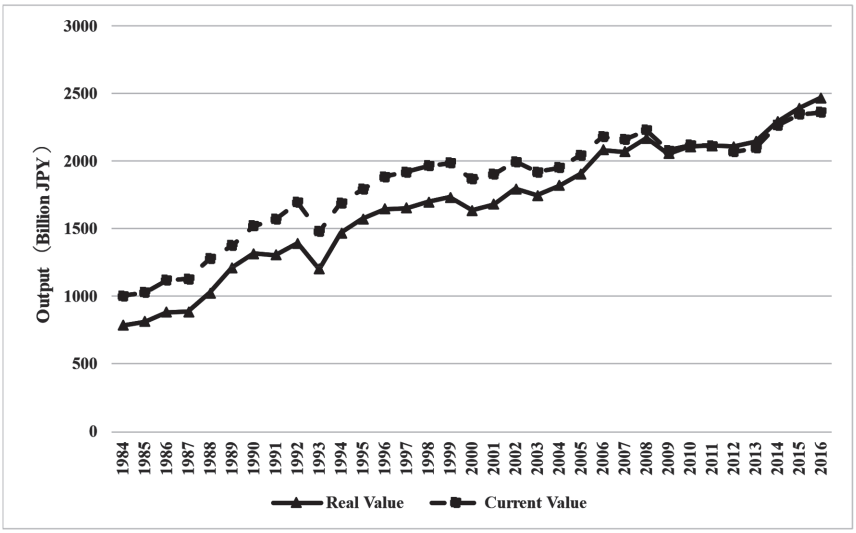
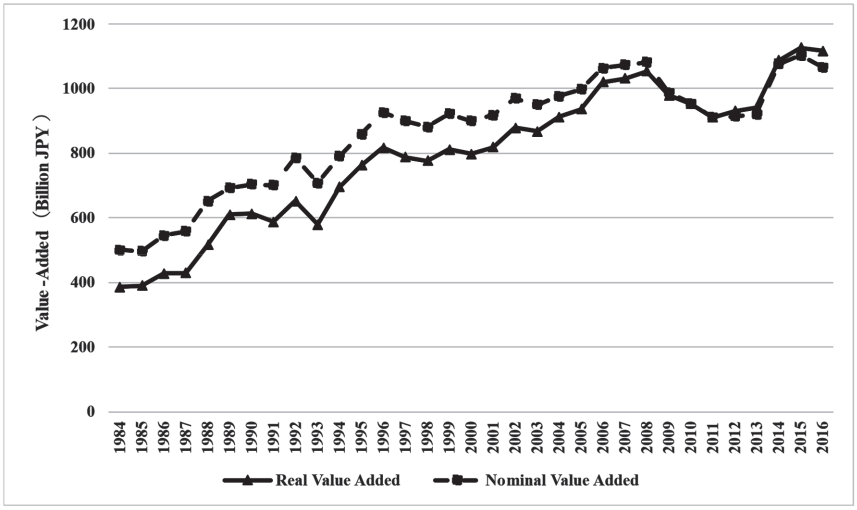


Figure 3. Value Added in MED-MI (Billion JPY)



Companies and stakeholders are often evaluated nominally. In the face of deflation, real value added increased by 38% between 1995 and 2008, while nominal value added increased by only 25%. In the MED-MI, therefore some people appear to think that revenues have not risen sufficiently despite the increase in production.

On the other hand, deflation also means that healthcare services with medical devices are provided at a low cost and the contribution to the public's health is immeasurable. Thus, it is necessary to simultaneously discuss the appropriate price of medical equipment and the spread of inexpensive medical services.

Certainly, MED-MI is growing, but the growth rate is declining. The growth rate of value added has also declined in recent years. In real terms, the annual growth rate was 5.7% before 2000 but has dropped significantly to 2.2% since 2000. After the global financial crisis occurred in 2008, value added declined drastically between 2008 and 2013, but it is unlikely that the financial crisis significantly impacted the frequency of MED-MI use. One interpretation is that Japan faced severe appreciation of the yen during this period. The strong yen may therefore have affected medical equipment exports.

Thus far, output data for MED-MI has been constructed. The factors MED-MI requires for output as input factors will now be estimated below.

First, labour input in MED-MI was measured. Labour input is evaluated in person-hours, the number of workers multiplied by the numbers of hours worked. The number of workers is taken from the Census of Manufacture. The labour hours are taken from SNA. Figure 4 shows the person-hour index.

Figure 4. Person-hour Index (2011=1)

The person-hour index declined until the early 2000s but has since increased; labour input increased by approximately 10% in 2016 compared to 2011.

Next, another factor required for production, capital, was estimated. Capital input is the balance of goods necessary for production held by a company and refers to goods that can be used repeatedly. Examples include tangible assets such as machinery, buildings, and vehicles. It also has intangible assets such as ideas and software, which are difficult to ascertain. Therefore, only R&D is included in capital stock. Capital accumulation is defined as follows:

$$K_t^j = I_t^j + \left(1 - \delta^j\right)K_{t-1}^j \quad (2),$$

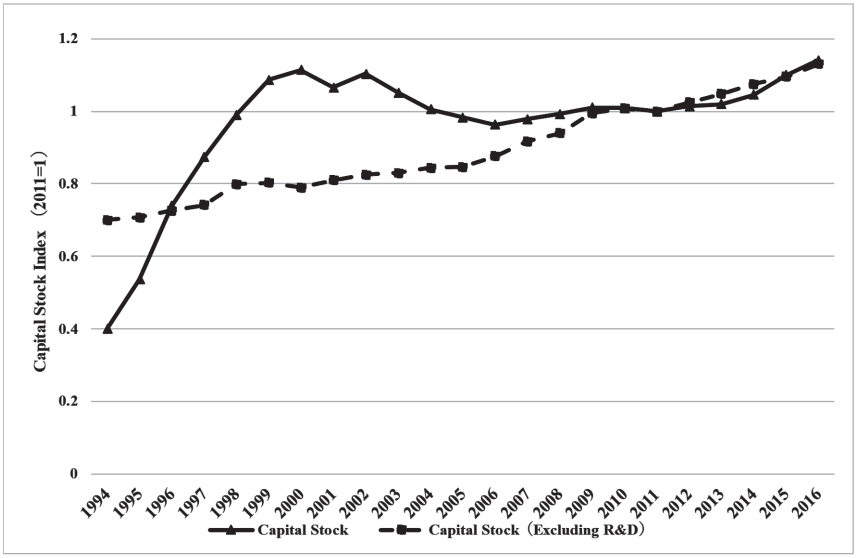
where I^j, K^j, and δ^j are investment (capital formation), capital stock, and depreciation for the jth asset. While SNA defines many assets the Census of Manufacture does not include all assets. Thus, only three tangible assets were measured: structures, constructions, machinery, and other assets. Other assets include transport equipment and tools. It was assumed that the other assets were mostly transport equipment. Here, it is also assumed that the expenditure for these assets are tangible capital investments. These expenditures are current values, but a real value for capital accumulation is needed. The capital goods deflators are taken from SNA. In addition, the depreciation rates are 3.76% (structure and construction), 17.01% (machinery), and 25.81% (other assets). These rates were estimated using the SNA average.

Recently, researchers have focused on both tangible and intangible assets. One of the representative intangible assets is R&D. In SNA, R&D, software, mineral exploration and evaluation, and entertainment originals are considered intangible assets. However, since we cannot measure R&D and software from the Census of Manufacture, R&D expenditure in MED-MI can only be estimated. Moreover, the medical instruments and apparatus category given in the Basic Survey of Japanese Business Structure and Activities (Ministry of Economy, Trade, and Industry) incur R&D expenditures. The rate of R&D expenditure to value added to medical instruments and apparatus was then calculated. This rate in other industries that constitute MED-MI was multiplied by the

value added. The deflator of R&D expenditure is from SNA, and the depreciation rate is 15.76%[3].

Capital was accumulated from 1984, but data from 1984 to 1993 was not used to estimate the robustness of capital stock. Figure 5 shows the estimated index of capital stock in MED-MI.

Figure 5. Capital Stock Index



Excluding R&D (tangible assets only), capital stock is growing. In Japan, little capital stock growth occurred during the long period of stagnation known as the 'lost two decades.' However, capital stock growth in MED-MI is surprisingly high.On the other hand, the picture is different for more general capital stock, which includes R&D. Capital stock (including R&D) increased rapidly until 2000, after which it stagnated. It has also increased again since 2014. However, capital stock in 2016 was only at the same level as in 2002.

The significant difference between the capital stock of MED-MI and the stock of tangible assets is due to R&D. MED-MI is an R&D-intensive industry, and R&D stock accounts for more than 60% of the total capital stock. Therefore, when R&D investment declines, capital stock declines rapidly. owing to the high rate of R&D depreciation.

As R&D investment is expenditure on innovative technologies and products, MED-MI may aggressively invest in R&D. In the early 2000s, the Non-Performing Loan problem was severe. In addition, bursting of the IT bubble and other factors may have made it difficult to raise funds. Moreover, declining revenues and other factors are related to declines in R&D investment. Since 2013, however, monetary easing has improved access to finance and increased capital stock.

As argued by Ogawa and Suzuki (1998), and Suzuki (2001), companies in Japan have traditionally raised funds by using land as collateral. Here, landholdings, which are not directly used for production but are thought to be an asset, are considered. While purchased assets secure tangible asset investments, a typical feature of R&D is that it cannot be secured by intangible assets. Therefore, repayability is necessary for investments in intangible assets[4]. As MED-MI is an R&D-intensive industry, this financial constraint is considered more severe. Therefore, the market value

3 The depreciation rate of R&D is estimated from the SNA average.

4 See Brown and Petersen (2011).

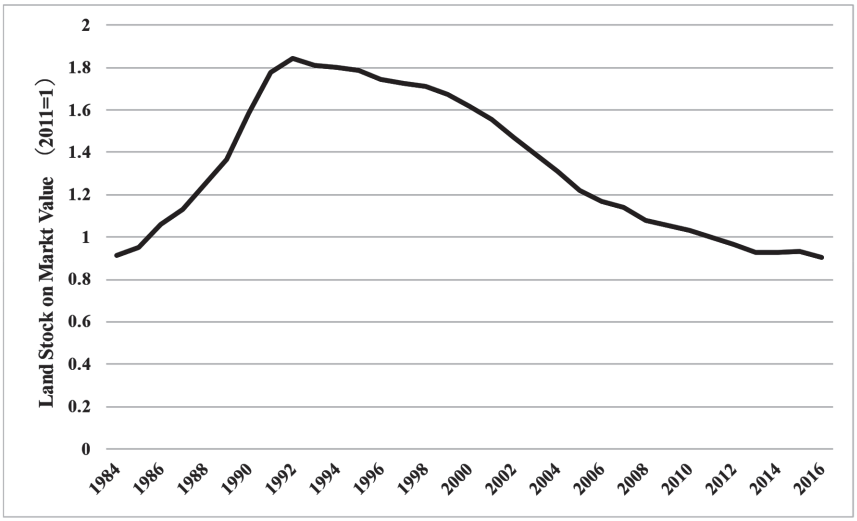
stock of land held by the MED-MI was measured.

Measuring land stock held by MED-MI at market-value[5] follows Ogawa and Suzuki (1998):

$$L_t = L_{t-1} \times \frac{P_t}{P_{t-1}} + (BL_t - RL_t) \quad (3).$$

where *BL*, *L*, *RL*, and *P* mean book-value land stock, market-value land stock, retirement land stock, and price level of the land. Figure 6 shows the effect of land stock on market value holdings by MED-MI.

Figure 6. Land Stock at Market Value (2011=1)



From 1984 to 1992, the market value stock of the land increased. The Japanese economy was in a bubble during this period because the land price was extremely high. In addition, MED-MI also increased land purchases due to the impact of prices. Indeed, between 1984 and 1992, land prices rose by 55%, whereas the market value of stocks held by MED-MI increased by 107%.

However, since 1992, the market value of the land stock has declined. This was due to the collapse of the bubble economy, which caused land prices to fall. However, from 1992 to 2013, land prices fell by 56%, whereas the land stock at market value decreased by 50%. Hence, MED-MI did not sell land to raise funds but continued to buy land.

Such a sudden depreciation of the land stock at market value leads to damage to the value of the collateral. Therefore, it is highly likely that MED-MI struggled to raise funds during this period. In addition, the land stock at market value in 2016 was always low. This means fundraising in 2016 may have been more challenging than in 1984. This is the context in which MED-MI has invested in tangible assets and R&D.

3. Productivity

This section presents the growth account theory used to measure economic growth. Economic growth occurs not only through labour input and capital but also through productivity growth.

5 By valuing land at market value, the price at which the land is actually sold is considered.

Productivity, which does not depend on these inputs was estimated. Here, the Cobb-Douglas production function is assumed as:

$$Y_t = A_t\, K_t^{\alpha}\, L_t^{1-\alpha} \tag{4},$$

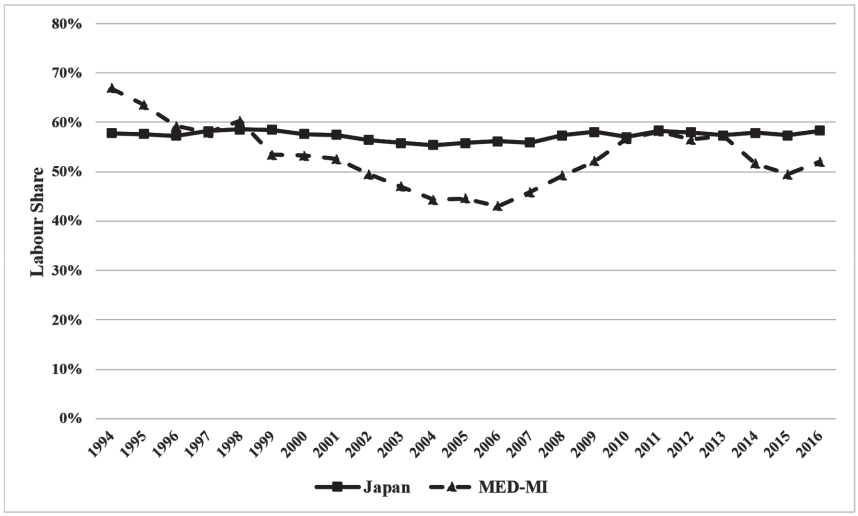
where Y_t is the real output, K_t and L_t are capital and labour inputs, A_t denotes the level of Total Factor Productivity (TFP), and α ($0 < \alpha < 1$) is the capital share.

From equation (4), following Solow (1956, 1957), Swan (1956), and Jorgenson and Griliches (1967), the growth rate of output using the capital and labour growth rates are obtained:

$$g_Y = g_A + \alpha\, g_K + (1-\alpha)\, g_L \tag{5},$$

where $g_{\cdot} = d \ln_{\cdot} / dt$ ($X = Y, A, K, or\ L$). From equation (5), TFP equals the growth rate of output excluding the growth rate of contribution of capital input ($\alpha\, gK$) and growth rate of contribution of labour input ($(1-\alpha)\, g_L$). To measure the contribution of labour and capital growth, labour share was used, which is the employer compensation divided by nominal value added. However, the Census of Manufacture does not include employee benefits. Employee benefit was then estimated as the total wage rate of an adjusted multiplier. This multiplier is (total wages + employee benefit) / value added. Figure (7) shows the labour share in MED-MI.

Figure 7. Movements of Labour Share

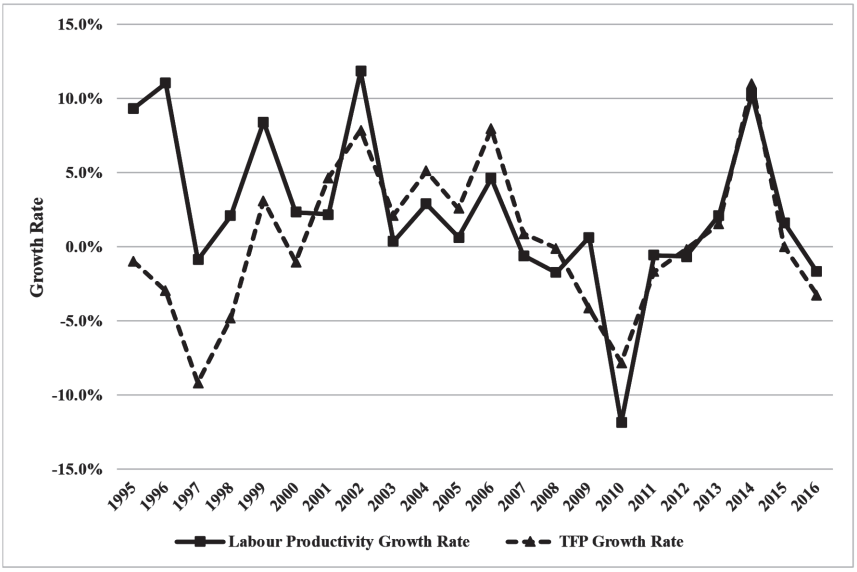


Note: From SNA and author estimation.

The labour share in Japan[6] is stable at approximately 58%. By contrast, labour productivity in MED-MI has been relatively dynamic. In 1994, the labour share was the highest, but in 2007, this trend declined. After 2007, the labour share approached Japan's average. Other countries have observed a declining trend in labour share. Karabarbounis and Neiman (2014) point out that the labour share decline is caused by high-performance and cheaper computers, improved information technology (IT) thus replacing labour work. Figure 8 shows the growth rates of labour productivity and TFP.

6 Labour share in Japan is (employer compensation + Taxes on Production and Imports)/ GDP by SNA.

Figure 8. TFP and Labour Productivity Growth Rates



Before the global financial crisis, the TFP growth rate was higher than labour productivity. The labour productivity growth rate was high before the global financial crisis but decreased after this crisis. On the other hand, the TFP growth rate was lower than the labour productivity rate before the early 2000s.

Beginning in 2013, an economic policy known as Abenomics was implemented. This led to a temporary pickup in productivity, which slumped again in 2015[7]. The differing movements in total factor productivity and labour productivity are due to differences in the input factors considered. The TFP growth rate is the growth in value added minus labour and capital contributions. Table 2 presents the growth rate of the value added of these contributing factors.

Table 2. Factor Decomposition of the Growth Rate of Value Added

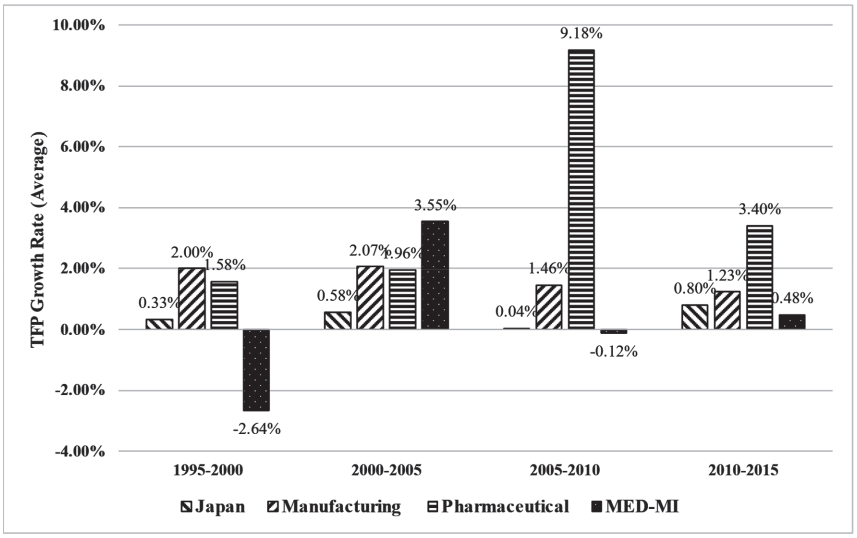
	1995-2000	2000-2005	2005-2010	2010-2015	1995-2005	2005-2015
Growth Rate of Value Added	2.09%	1.85%	1.01%	2.32%	2.36%	2.10%
Capital Contribution	6.64%	-0.90%	-0.02%	0.68%	3.02%	0.37%
Labour Contribution	-1.91%	-0.79%	1.15%	1.16%	-1.25%	0.82%
TFP Contribution	-2.64%	3.55%	-0.12%	0.48%	0.59%	0.91%

The growth of value added stagnated from 2005 to 2010 but averaged around 2%, indicating that MED-MI had very high growth. In contrast, Japan's GDP growth rate averaged 0.8% from 1995 to 2016. Capital contribution grew at a very high rate from 1995 to 2000 but declined and has barely grown since 2000. In particular, the growth rate of capital contribution was negative in the 2000s, and this capital slump led to a recession in the growth rate of value added. However, the labour contribution was negative until 2005, but its growth rate later exceeded 1%.

7 Why do economic phenomena such as the financial crisis and Abenomics affect the healthcare sector? One possible reason is due to trade. However, analysing what is actually occurring is a subject for future work.

From 1995 to 2005, capital and TFP were the growth drivers. However, from 2005 to 2015, there was a turnaround, with TFP accounting for approximately half of the growth. Thus, it can be said that MED-MI growth was dependent on an increase in TFP. In addition, the capital contribution was approximately 20%, and the stagnation of capital accumulation restrained the growth of value added. Figure 9 shows the TFP growth rates of MED-MI and other industries.

Figure 9. Industry Comparison of TFP Growth Rate



Note: JIP Database 2021[8] and author estimation.

Thus MED-MI experienced high growth during the 2005-2010 period. However, the rest of the period saw shallow growth, not only in the manufacturing sector but also in Japan. From 2005 to 2010, the pharmaceutical industry, in the same medical sector, grew by 9%. Even for the entire period, the growth rate differed from that of MED-MI by approximately 2%. Therefore, it is not the medical field that is stagnant; the stagnation is a problem specific to MED-MI.

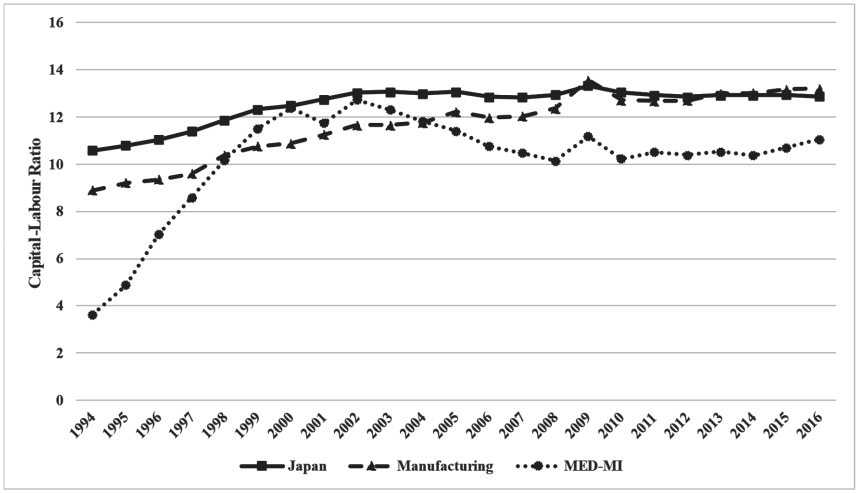
How should the relationship between TFP and labour productivity be considered? The focus is placed on the relationship between TFP and labour productivity to answer this question. This relationship is expressed as follows:

$$g_{LP} = g_{TFP} + \alpha g_{K/L} \quad (6),$$

where g_{LP}, g_{TFP}, and $g_{K/L}$ represent the growth rate of labour productivity, the growth rate of TFP, and the growth rate of the capital-labour ratio. The capital-labour ratio implies that capital is divided by the person-hour labour force. This equation means that movement the capital-labour ratio affects labour productivity growth through the TFP growth rate. Figure 10 shows the movement in the capital-labour ratio.

8 https://www.rieti.go.jp/jp/database/JIP2021/

Figure 10. Movements in the Capital-Labour Ratio



Note: SNA and author estimation.

In Japan, the capital-labour ratio has stagnated since 2000, and the manufacturing sector has stagnated since the global financial crisis (2009). In contrast, MED-MI underwent a more significant change as: the capital-labour ratio rose rapidly until 2000. In the 2000s, however, the capital-labour ratio declined. This decline in the capital-labour ratio may have caused a decline in labour productivity.

Slow capital accumulation has caused a decline in the capital-labour ratio. This implies sluggish capital investment. Investment in intangibles, as typified by R&D, is also weak. Since MED-MI is an R&D-intensive industry, its capital stock has not grown due to sluggish R&D investment.

Sluggish investment can create problems not only for the capital-labour ratio but also for production. Weak investment means that old equipment is not replaced by new equipment. This new equipment embodies new technology which old equipment does not have. Hence, production efficiency may be declining.

TFP often indicates technological progress, but it is unrealistic to achieve progress using old production technologies; sufficient investment is essential to promote MED-MI and produce world-class medical devices.

4. R&D efficiency

This section focuses on total factor productivity (TFP): an increase in TFP increases the economy's growth rate as a whole, that is, the growth rate of value added. The previous section confirms that an increase in TFP also increases labour productivity. Therefore, the challenge is to increase TFP.

The idea that TFP captures a certain percentage of technological progress is common. Working more efficiently with new technologies or successfully using production equipment through ideas is included in TFP. The source of these ideas and new technologies in R&D investment is expenditure on equipment, materials, and others used in R&D. Here, the focus is shifted to the relationship between TFP growth and R&D. The endogenous growth theory, one of the theories of economic growth, formulates the relationship between R&D and TFP. Griliches (1998) expresses it as follows;

$$g_{TFP} = R_{R\&D} \times S_{R\&D} \quad (7),$$

where $R_{R\&D}$ and $S_{R\&D}$ are the rate of return on R&D, and R&D intensity. From equation (7), the rate of return on R&D is evaluated by dividing the growth rate of TFP by R&D intensity. R&D intensity refers to the share of R&D expenditure in value added. Figure 11 and Table 3 show the rates of return on R&D.

Figure 11. Rate of Return on R&D

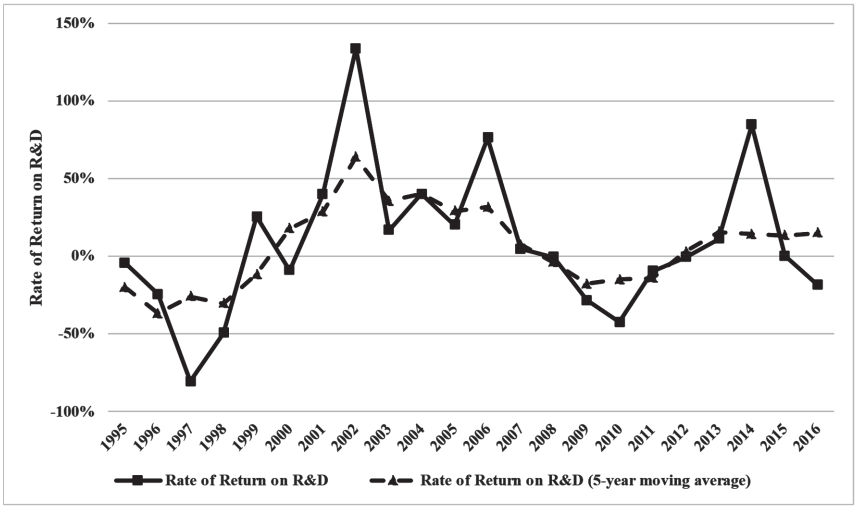


Table 3. Rate of Return on R&D

	All terms	1995-2005	2005-2016	2000-2008	2012-2016
Rate of Return on R&D	8.23%	9.64%	6.82%	35.56%	15.23%
Rate of Return on R&D (5-year moving average)	6.16%	7.98%	4.34%	27.59%	12.09%

TFP often takes a negative value, resulting in a lower R&D rate of return. However, comparing 1995-2005 and 2005-2016, the latter was 30-50% lower than the former. Between 2000 and the global financial crisis (2009), and 2012-16, after the Great East Japan Earthquake, the latter was less than half of the former. This significant reduction in the rate of return is problematic.

The relationship between TFP and R&D is sometimes considered to concern R&D efficiency rather than R&D profitability. It is a structure in which R&D activities increase TFP through R&D efficiency, as follows:

$$g_{TFP} = E_{R\&D} \times L_{R\&D} \quad (8),$$

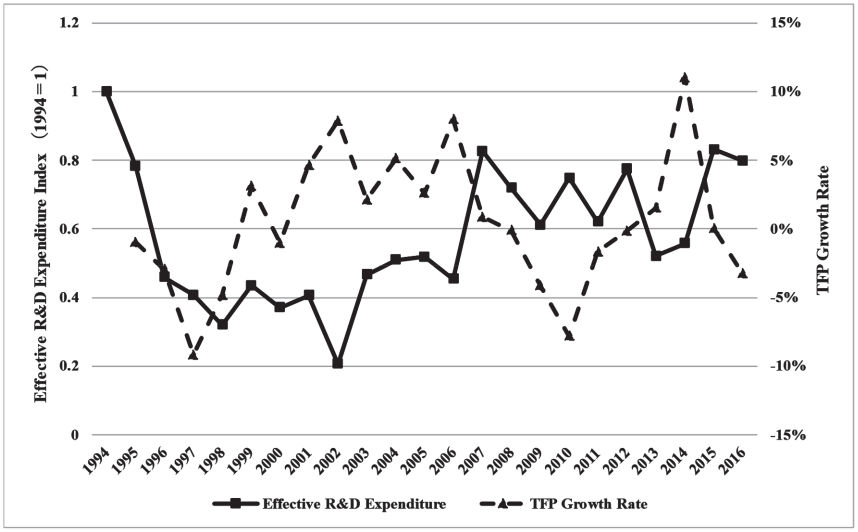
where $E_{R\&D}$ and $L_{R\&D}$ represent the efficiency of R&D and the number of R&D workers.

R&D workers often signifies that a large number of researchers are employed. However, despite an increase in the number of researchers, the TFP growth rate declined. Bloom et al. (2020) pointed out that R&D efficiency is declining. They explain the decline in R&D efficiency within the framework of economic theory. The authors conducted their analysis using effective R&D

expenditure, where R&D expenditure is evaluated in terms of researchers' wages rather than the number of researchers. As a result, they confirm that R&D efficiency has declined significantly in the US healthcare as well as in agriculture and the high-tech industries. Miyagawa and Ishikawa (2019) used these ideas in their analysis. Their results confirm that R&D efficiency is declining in Japanese manufacturing, albeit more slowly than in the USA.

Figure 12 shows the relationship between effective R&D expenditure and the TFP growth rate in MED-MI.

Figure 12 Relationship Between Effective R&D and TFP Growth



There is, no significant difference between the wages of researchers and general workers in Japan. The average MED-MI wage was used as the researcher's wage. Since 1998, TFP has remained stable, except for around 2009. However, effective R&D expenditure is at a lower level than that in 1994. Since 1997, effective R&D expenditure has risen, but its value in 2016 was lower than in 1994. Table 4 shows that R&D efficiency in MED-MI is evaluated through effective R&D.

Table 4. R&D Efficiency (1995-2000 = 1)

	2000-2005	2005-2010	2010-2016	2000s	2010s
R&D Efficiency	1.23	0.86	0.76	1.09	0.76

R&D efficiency in1995-2000 was standardised as 1. In 2000-2005, R&D efficiency was higher than in 1995-2000. However, since 2005, R&D efficiency has declined. In 2010-2016, efficiency fell by 24% compared to 1995-2000. This means that R&D was more successful in the 2000s than the 2010s. R&D profitability was also twice as high in the 2000s, when MED-MI enjoyed the benefit of innovation, as in the 2010s. Since 2010, the problem has been the stagnation of R&D profitability and efficiency, indicating stagnant TFP growth rates. Therefore, it is necessary to increase R&D efficiency and profitability to develop MED-MI.

5. Conclusion

The statistical data on MED-MI in this study were initially generated and then analysed for productivity. Four main results were obtained. First, MED-MI always faces a price decline (deflation). Therefore, real value added exceeds nominal value added. Second, MED-MI is an R&D-intensive industry. However, R&D investment has stagnated, and the capital stock has not increased. This may be due to insufficient financing for R&D investment, and funding needs to be discussed in MED-MI. Third, labour productivity growth remained high until the early 2000s. Since then, however, labour productivity growth has stagnated. This stagnation in the labour productivity growth rate can be attributed to the stagnation of the capital-labour ratio. Finally, the sluggish TFP growth rate is explained by the decline in R&D efficiency and profitability. Aggressive R&D investment is needed, but market structures and institutions may have contributed to these declines, which will need to be discussed in the future.

The stagnation of the capital-labour ratio is not a problem unique to Japan. According to Miyagawa and Ishikawa (2021), developed countries have experienced a slump in the capital-labour ratio since the global financial crisis. A shift to investment in intangible assets can explain the capital-labour ratio slump. Intangible assets depreciate rapidly and are challenging to grasp. Kim, Gong, and Fukao (2019) argue that Japan's long-term stagnation is due to slow capital accumulation. MED-MI has a high growth rate of value added but a sluggish TFP growth rate and investment. MED-MI urgently requires investment promotion and deregulation to improve its growth.

There can be no evidence-based policymaking without data. The indicators in this study are inadequate; regular and continuous data publications are necessary to develop MED-MI. For this reason, our future works will include improving the data and creating data that take into account software and other intangible assets that could not be measured in this paper. Moreover, as a further future task, we would also like to develop an input-output table.

References

Bloom, Nichols., Charles I. Jones, John Van Reenen, and Michael Webb (2020) "Are Ideas Getting Harder to Find?" *American Economic Review*, Vol.110(4), pp.1104-1144.

Brown, James R., and Bruce C. Petersen (2011) "Cash Holdings and R&D Smoothing," *Journal of Corporate Finance*, Vol.17, pp.694-709.

Griliches, Zvi. (1998) "Returns to R&D Expenditures in the Private Sector," Ch.3 In: Z. Griliches, *R&D and Productivity: The Econometric Evidence*, University of Chicago Press, pp.49-81.

Ishikawa, Takayuki. (2021) "Research on the Statistics of Medical Device Industry in Japan -Developing Statistics and Analysis Performance-," *MDSI Research Paper*, No.32.

Jorgenson, Dale W., and Zvi Griliches (1967) "The Explanation of Productivity Change," *Review of Economic Studies*, Vol.34(3), pp.349-383.

Karabarbounis, Loukas. and Brent Neiman (2013) "The Global Decline of the Labor Share," *The Quarterly Journal of Economics*, Vol.129 (1), pp.61-103.

Kim, Young Gak., Hyeog Ug Kwon, and Kyojo Fukao (2019) "The origins of Japan's economic stagnation and necessary policies: An analysis based on the JIP 2018," *RIETI Policy discussion paper Series 19-P-022* (in Japanese).

Miyagawa, Tsutomu., and Takayuki Ishikawa (2019) "On the Decline of R&D Efficiency," *RIETI Discussion Paper Series: 19-E-052*.

Ogawa, Kazuo., and Kazuyuki Suzuki (1998) "Land Value and Corporate Investment: Evidence from Japanese Panel Data," *Journal of Economics*, Vol.129(2), pp.61-103.

Solow, Robert M. (1956) “A Contribution to the Theory of Economic Growth,” *Quarterly Journal of Economics*, Vol.70(1), pp.65-94.

———, (1957) “Technical Change and the Aggregate Production Function,” *Review of Economics and Statistics*, Vol.39(3), pp.312-320.

Suzuki, Kazuyoshi. (2001) *Capital Investment and Financial Markets*, University of Tokyo Press (in Japanese).

Swan, Trevor. W. (1956) “Economic Growth and Capital Accumulation,” *The Economic Record*, Vol.32(2), pp.334-361.

Appendix: Statistics

Statistics on Medical Device Manufacturing Industry in Japan

Name	Output		Value Added		Total Wage	Employee benefit	Labour	Person-hour	Nominal Investment				
	Current Value	Real Value	Current Value	Real Value						Structures and Constructions	Machinery and Equipment	Others	R&D
Unit	million JPY	million JPY	million JPY	million JPY	million JPY	million JPY	Number	1000 hours	million JPY	million JPY	million JPY	million JPY	million JPY
1994	1691639.00	15002.90	790516.00	701097.00	354574.00	174102.80	92748.00	186236.21	260940.34	15861.00	28419.00	13229.00	203431.34
1995	1790921.00	16030.39	858453.00	768394.29	370778.00	174736.64	92120.00	185985.53	222320.47	14557.00	26387.00	13799.00	167577.47
1996	1885552.00	16743.86	926915.00	823108.09	363746.00	185901.01	88467.00	178418.56	162390.12	19484.00	28988.00	13487.00	100431.12
1997	1919385.00	16822.08	900221.00	788981.40	364567.00	156852.51	86623.00	172519.50	152051.79	17251.00	28427.00	15313.00	91060.79
1998	1964800.00	17177.92	881617.00	770783.09	372097.00	159704.84	83497.00	165049.02	165075.92	29305.00	43779.00	16179.00	75812.92
1999	1984561.00	17495.95	922586.00	813354.71	351534.00	141016.31	81602.00	160091.84	155608.00	15813.00	25379.00	14742.00	99674.00
2000	1869409.00	16523.02	899198.00	794768.18	344753.00	133708.81	77373.00	152825.94	132468.12	8944.00	23996.00	11654.00	87874.12
2001	1903225.00	16965.04	918540.00	818771.76	346766.00	135734.81	78039.00	154040.07	158736.26	20209.00	28776.00	13940.00	95811.26
2002	1994981.00	18088.11	970320.00	879770.29	346763.00	133118.00	74552.00	147061.61	110848.40	17058.00	29379.00	13216.00	51195.40
2003	1920455.00	17577.06	950232.00	869704.36	318738.00	127453.43	72320.00	144852.02	161764.71	13755.00	26039.00	12519.00	109451.71
2004	1894887.00	17736.09	977266.42	892600.60	305241.00	117154.81	72272.00	144418.99	174425.45	10584.00	36993.00	12432.00	114416.45
2005	1983603.00	18515.76	998216.27	908885.55	312056.00	121682.27	73264.00	146141.21	169978.85	13603.00	25233.00	13824.00	117318.85
2006	2117421.00	20207.19	1062876.78	990049.83	327889.00	118814.44	75655.00	152024.79	174583.62	20421.00	33914.00	15674.00	104574.62
2007	2157985.00	20638.61	1073470.00	1026648.99	359640.00	132898.11	79109.00	158573.60	279865.86	24831.00	40181.00	15185.00	199668.86
2008	2227990.00	21683.95	1081160.00	1052240.73	383130.00	149202.84	85603.00	165405.13	243526.52	21085.00	33274.00	17958.00	171209.52
2009	2079401.00	20585.34	988050.00	978134.68	353479.00	161909.34	82648.00	152767.66	231728.53	34528.00	42084.00	15831.00	139285.53
2010	2116685.00	21036.16	954424.00	948530.90	375010.00	166366.69	85812.00	166814.53	242277.98	22443.00	29830.00	16060.00	173944.98
2011	2115544.00	21155.44	910613.00	910613.00	389207.00	140342.70	82335.00	161047.98	210627.49	14661.00	27221.00	12663.00	156082.49
2012	2070161.00	21043.20	913245.00	928314.35	377453.00	138549.10	84993.00	165290.30	256606.25	19581.00	39248.00	14756.00	183021.25
2013	2095730.00	21416.47	920108.00	940267.38	389737.00	137111.77	83690.00	163909.43	204547.75	25879.00	34222.00	15459.00	128987.75
2014	2264637.00	22854.21	1076675.00	1086556.53	416954.00	138629.91	86749.00	170881.44	223113.86	29213.00	34012.00	17378.00	142510.86
2015	2345000.00	23898.38	1103161.00	1124254.28	398048.00	148018.62	87926.00	173959.02	277742.42	25614.00	36888.00	14947.00	200293.42
2016	2361463.00	24586.37	1066751.00	1110647.77	406093.00	148864.55	88988.00	174752.10	281987.70	28882.00	41242.00	18181.00	193682.70

Statistics on Medical Device Manufacturing Industry in Japan (Continued)

Name	Real Investment					Capital Stock					Land Market Value Stock	Total Factor Productivity	
		Structures and Constructions	Machinery and Equipment	Others	R&D		Structures and Constructions	Machinery and Equipment	Others	R&D		Production Based	Value Added Based
Unit	million JPY	million JPY	million JPY	million JPY	million JPY	million JPY	million JPY	million JPY	million JPY	million JPY	million JPY		
1994	251579.99	15943.82	24648.92	8596.04	202391.21	678323.43	257534.16	139015.43	33229.38	516476.82	272234.53		
1995	213005.93	14719.97	23182.72	8366.28	166736.96	910079.55	262570.84	138537.72	33019.16	605742.25	269725.52	-0.0351239	-0.0097100
1996	152951.28	19643.03	25543.27	8302.62	99462.36	1255353.56	272341.21	140501.88	32799.54	614343.27	263521.01	-0.0550232	-0.0297839
1997	141606.49	17298.91	25073.55	9774.40	89459.63	1483343.64	279400.09	141662.01	34108.38	611651.41	261016.60	-0.0447056	-0.0917114
1998	153953.03	29869.34	38582.13	10442.66	75058.90	1680582.77	298763.98	156133.27	35747.67	594962.59	258540.28	-0.0039297	-0.0481979
1999	148811.93	16353.10	22768.81	10248.08	99441.94	1844190.86	303883.56	152328.19	36769.28	605160.15	253051.85	-0.0043997	0.0310160
2000	126488.23	9236.14	21842.17	7886.60	87523.33	1891786.41	301693.67	148244.10	35165.72	601909.45	244061.09	-0.0443585	-0.0102604
2001	154422.04	21037.08	26668.26	10394.61	96322.09	1809593.23	311387.07	149681.22	36484.06	607945.12	235202.22	0.0431517	0.0465064
2002	107643.78	18032.63	27180.75	10739.15	51691.26	1873553.69	317711.54	151386.22	37806.68	568444.61	222339.12	0.0707178	0.0784735
2003	160188.02	14515.72	24883.03	10764.96	110024.31	1784062.14	320281.31	150503.32	38813.73	593202.23	210057.87	0.0039879	0.0211405
2004	171321.64	11158.84	34461.67	10848.94	114852.20	1707538.27	319397.57	159349.32	39644.85	619074.09	197731.35	0.0342113	0.0511901
2005	168027.62	14167.18	24164.49	12276.51	117419.44	1668227.97	321555.40	156392.55	41689.03	643632.42	184721.40	0.0507000	0.0257593
2006	170849.66	21022.42	32112.94	14260.13	103454.17	1635212.83	330487.34	161887.48	45189.22	650541.73	176442.24	0.0813609	0.0794807
2007	274259.16	25145.20	38224.06	13619.77	197270.13	1661534.67	343206.22	172558.29	47145.65	750230.60	172253.78	-0.0064976	0.0086771
2008	235126.11	20381.47	31874.59	16093.93	166776.11	1679883.76	350683.13	175063.46	51071.29	804472.13	163343.26	0.0235888	-0.0011979
2009	232197.87	34302.06	40932.19	14990.40	141973.22	1710091.23	371799.50	186199.85	52880.19	825774.53	159653.34	-0.0204837	-0.0415203
2010	242237.15	22561.70	29550.71	15550.45	174574.28	1708937.06	380381.54	184059.35	54782.26	876482.63	155913.43	-0.0259189	-0.0783155
2011	210627.49	14661.00	27221.00	12663.00	156082.49	1693521.91	380740.20	179953.45	53305.96	901092.72	151120.84	0.0297179	-0.0167329
2012	256531.12	19587.94	39042.14	15000.42	182900.62	1717385.94	386012.31	188367.51	54548.11	948829.43	145958.23	-0.0261963	-0.0016245
2013	204199.88	25655.47	33639.80	15769.95	129134.66	1726822.93	397153.71	189947.16	56239.19	935639.68	140313.57	0.0199916	0.0152029
2014	220497.54	28408.08	33046.53	17543.13	141499.80	1772496.37	410628.81	190664.69	59266.99	936793.53	140112.60	0.0304055	0.1100347
2015	274217.31	24659.10	35468.67	14945.75	199143.80	1863893.02	419848.27	193682.23	58915.92	995418.29	140599.66	0.0107898	0.0002210
2016	279829.57	27896.19	39906.37	18181.78	193845.22	1933867.20	431958.17	200623.88	61891.51	1039950.77	136799.57	0.0079261	-0.0326320

Journal of International Economic Studies (2023), No.37, 23–37

Comparison of Reimbursement Pricing Systems for Medical Devices in Japan and Other Countries

Makoto Tamura[1] and Takuma Sugahara[2]
Graduate School of International University of Health and Welfare[1]
Hosei University Faculty of Economics[2]

Abstract

In this article, we discuss the current status of the reimbursement price system for medical devices in Germany, France, the UK, the US, and Australia, which are the reference countries for the "foreign price adjustment system" in determining insurance reimbursement prices, and also provide implications for Japan. While Germany, the UK, and the US generally have reimbursement systems where medical devices are reimbursed as part of lumpsum payment, in other countries, as with Japan's specified insurance medical devices, individual reimbursement prices are set. In countries that primarily implement lumpsum payments, there is a system of adding a certain period of reimbursement price increase to compensate for the decrease in medical institutions' revenue resulting from the price increase of improved products. In addition, there are other support systems for collecting clinical evidence, which serve as examples for future discussions in Japan to promote the appropriate introduction of new medical devices.

Keywords: medical devices, reimbursement pricing system, lumpsum payment, value-based pricing

JEL classification: **I28, K23, L51**

1 Outline and characteristics of reimbursement pricing systems for medical devices in other countries

1.1 Germany

The German health care system is based on a social insurance system in which approximately 87% of the population participates. Employees are enrolled in public health insurance (Gesetzliche Krankenversicherung), which is defined in Part 5 of the Social Code, on an occupational or regional basis. Employees above a certain income level, self-employed persons, civil servants, etc. are not obliged to join, but those who are not eligible for mandatory coverage are obliged to join private medical insurance, which is regarded as a de facto universal health insurance.[i] Public health insurance provides all medically necessary benefits in a comprehensive manner. There are two

i In principle, all people are covered by these public and private insurance programs, but those who are not covered by these programs due to poverty or other reasons are covered by social assistance (public funds) in accordance with the provisions of Part 12 (Social Assistance) of the Social Code and Part 8 (Assistance for Children and Juveniles) of the Social Code.

benefit principles: The "professional principle," which requires that benefits be commensurate with the general level of medical care and takes into account medical advances, and the "economic principle," which requires that benefits be provided in a cost-effective manner without going beyond what is necessary.

1.1.1 Reimbursement for Inpatient Care

In addition to Part 5 of the Social Code, the Hospital Funding Law and the Hospital Medical Fee Law provide the basis for hospital reimbursement. The Hospital Financing Act defines the framework for compensation of hospital costs, and the Hospital Medical Fee Act defines the specific mechanism. Under this structure, German hospitals are operated under a "dual financing system" and are financed basically from two sources. The costs of capital investment in hospitals are to be borne by the state as investment costs based on the state government's hospital plans and investment programs. While the costs of capital investment are generally excluded from reimbursement, recurring operating costs (personnel, drugs, various supplies, etc.) are covered mainly by public health insurance through a per-diagnosis grouping-based blanket reimbursement system (hereafter referred to as "DRG blanket reimbursement" [ii]). (Iwama, 2016).

The reimbursement system is positioned within a hospital-specific budget system. Each hospital negotiates annually with the health insurance fund (Krankenkasse) to determine the benefit structure and budget for each hospital. Based on the DRG evaluation coefficient data for the current year, the hospital negotiates and agrees on a budget for the type and amount of the comprehensive, additional, and other reimbursements for DRG cases to be implemented by the hospital in the following year, on a benefit basis. If there is an excess or deficiency between the budget and the income from reimbursement, an income adjustment is made.

Thus, within the budgetary framework, the DRG lumpsum payment system is used for budget agreements and ex post settlements. Budget negotiations are based on data from the DRG evaluation coefficient[iii], and revenues subject to revenue adjustments are calculated by the DRG lumpsum payment system (Tanaka, 2019).

1.1.2 Reimbursement for Medical Devices and Equipment

The DRG lumpsum payment encompasses the cost of all benefits for cases defined by the diagnosis group, and most medical devices and equipment are paid as DRG lumpsum payments.

Additional reimbursement covers benefits that cannot be properly paid by the DRGs, and the additional benefits will be included in the additional reimbursement catalog attached to the lumpsum payment agreement. This covers treatment of hemophilia, dialysis, blood products, and practices that use high-cost medical devices and therapies.

1.1.3 Examples of DRGs that Include Medical Devices

Table 1 shows examples of DRG classifications and reimbursement for percutaneous coronary intervention (PCI). The DRGs are subdivided according to the treatment, method, and patient

ii The DRG lumpsum reimbursement includes all inpatient medical expenses related to the relevant case. The difference is that DPC/PDPS in Japan only covers basic hospitalization charges, laboratory fees, drug costs, etc., and excludes surgery fees, medical devices used for surgery and high-cost drugs.

iii The maintenance and development of the DRG comprehensive system is legally stipulated to be carried out as a joint self-governing task of the Central Association for Disease Insurance, the Association of Private Medical Insurance, and the German Hospital Association. The Institute for Hospital and Medical Fee Research (InEK GmbH), which was jointly established by the three parties, is in charge of the research on the DRG system as a whole and the specific calculation of evaluation coefficients.

condition, and a reimbursement amount is defined for each.

First, reimbursement prices are determined by diagnosis and treatment, which are divided into three categories: Complex diagnosis (e.g., acute myocardial infarction), simple diagnosis (e.g., stable angina pectoris), and special procedures, and these are further classified by treatment method and by indicators to evaluate patient conditions.

Table 1.DRG Price List for Percutaneous Coronary Intervention (PCI) (2021)

Diagnosis/ treatment	Complex diagnosis (e.g., acute myocardial infarction)				Simple diagnosis (e.g., stable angina pectoris)				Special Procedures	
Treatment method	Three or more stents; and cutting balloon		Balloon catheter; 1-2 stents		Three or more stents; and Cutting balloon; 1 stent + IVUS/FFR		Balloon catheter; 1-2 stents		Rotablators, etc.	
PCCL*	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3
DRG (lumpsum payment)	F24A 9,829€ (9,829)	F24B 5,246€ (5,246€ in the previous year)	F52A 9,255€.	F52B 4,013€.	F56A 7,841€ (7,841)	F56B 3,788€ (3,788€ in the previous year)	F58A 6,473€ (6,473€ in the previous year)	F58B 2,921€ (2,921€ in the previous year)	F19A 11,903€ ($11,903)	F19B 5,981€ (5,981 million)

*PCCL: Patient Clinical Complexity Level, an index that evaluates a patient's condition based on complications and comorbidities.

1.1.4 Handling of New Medical Devices and Equipment

We will now look at the handling of newly approved products. The Federal Joint Committee (Gemeinsame Bundesausschuss: G-BA) is the main body that decides whether new medical technologies in the medical field are covered by insurance. The Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) evaluates the effectiveness and economic efficiency of health care systems and makes recommendations to the G-BA. In addition, Article 137c-1 of Part 5 of the Social Code stipulates that hospitals may provide new medical technology at the expense of the disease vault, unless the G-BA determines that the new technology is not necessary for the treatment of the insured person.

1.1.4.1 NUB (National Untimely Special Payment Scheme for New Innovations)

Newly approved medical devices are in principle paid as DRG lumpsum payments, but there is a special payment mechanism for a certain period of time through the NUB (Neue Untersuchungs und Behandlungsmethoden) mechanism when both the cost and the novelty of the product are high.

The NUB targets new breakthrough technologies that are not classified as DRGs, have been in use for less than four years, and whose costs cannot be covered by DRG reimbursement prices. The purpose of the NUB is to promote the use of new diagnostic and therapeutic technologies and to collect cost data.

The Institute of Hospital and Health Care Reimbursement (Institut für das Entgeltsystem im Krankenhaus: InEK) selects the applicable technologies, and medical institutions wishing to use the technologies negotiate with the disease vaults individually, including the availability and budget of the technologies. The target medical institutions are mainly university hospitals and other advanced medical institutions.

The term is renewable for one year, but after the NUB ends, new DRGs may be made or additions may be made, and so on.

1.1.4.2 Erprobungsstudie (Clinical Research Support Program)

In addition to the NUB, there is also a program (Erprobungsstudie) in which the government and companies provide funds to conduct clinical research on technologies that are expected to be effective and safe but are not covered by reimbursement due to lack of evidence. This is considered to be similar to the Advanced Medicine rule (Senshin Iryo) in the Japanese balanced billing reimbursement system.

This program may be based on applications from companies or designated by the G-BA. In the case of applications from companies, the G-BA will select which of the programs will be covered, and the costs associated with the research will be borne by the company and the costs associated with the treatment will be covered by the health insurance funds.

In the case of designation from the G-BA, the cost burden on the company will be limited, as it may be in the early stages of the NUB process described above or in checking the feasibility of the practice.

1.1.5 Quality Assurance and Evaluation

Quality assurance and evaluation is a task that many countries with lumpsum payment systems address. Germany also has a variety of initiatives, and, in relation to medical devices and equipment, each hospital is required to record defined "quality indicators" for specific benefits. Quality indicators, for example, in the case of pacemaker implantation, are defined as operative time, x-ray exposure time, perioperative complications, intracardiac signal amplitude, and in-hospital mortality. This data is aggregated and evaluated at the federal and state levels and fed back to each hospital. When peculiar data are discovered in the states, discussions are held or quality improvement measures are discussed with medical institutions (Matsumoto (2015)).

1.2 France

The French medical security system can be broadly classified into the compulsory "basic system" (public medical insurance), the voluntary "supplementary system" (supplementary medical insurance), and "universal medical benefits." Thus, the core of health care coverage is the medical insurance system. In addition to the general system for workers in the private sector, there are various occupational insurance systems, such as the self-employed social system for the self-employed and the agricultural system for farmers, which together with other systems based on the social insurance system achieve universal coverage. The supplemental system, which is the second level of the basic system, is a voluntary system that covers the portion of out-of-pocket expenses not covered by the basic system, but there is also a support system to reduce the burden of insurance premiums. Currently, more than 90% of the population is enrolled in some kind of supplementary system, which, together with the basic system, forms the foundation of the medical security system. Those who are not eligible for mandatory coverage under the basic system are covered by the universal health benefits system[iv].

1.2.1 Reimbursement for Inpatient Care

The reimbursement structure for services provided in medical facilities can be divided into

---

iv Universal health care benefits are intended to provide free or near-free health care to those who for some reason are not covered by public health insurance or who are covered by public health insurance but are unable to sign a contract with a supplementary benefits organization (Matsumoto: Health Care System Reform, p. 103).

three main categories. The first is the cost of the hospital stay, the second is the cost of the services provided, such as surgical procedures and advanced treatments, and the third is the cost of expensive drugs and medical devices. For the first part, which accounts for the largest proportion of hospitalization costs, the fees for physicians, surgeons, obstetricians, and dentists are calculated as a comprehensive evaluation per hospitalization based on the diagnosis group classification (Groupe homogène de séjour, or GHS), the French version of DRGs. In principle, the cost of drugs and medical devices during hospitalization are included in the comprehensive evaluation, but the cost of surgery, procedures, and the use of certain expensive drugs and medical devices are paid on a piece-rate basis based on prices determined separately from the GHS.

1.2.2 Reimbursement for Medical Devices and Equipment

The EU Directive is the regulatory basis for approving the marketing of medical materials and devices. Medical devices are classified into four levels according to their level of risk. Class I devices, which have the lowest risk, can be sold only after the manufacturer itself sets the regulatory level, while Class II and higher products can be sold only after they are certified as conforming to the quality certification mark (CE Mark) of a third-party organization in the EU.

For medical devices not included in the GHS, there is a pricing system called "LPP (liste des produits et prestations)," similar to Japan's Special Designated Treatment Material (STM), which is different from the lumpsum payment (for more on STM in Japan, see Tamura et al. (2019)).

In determining whether or not there is a reason for additional reimbursement as LPP, the criteria are 1) rapid technological innovation, 2) the price is so high that it does not fit in with lumpsum reimbursement, or 3) the number of eligible patients is small and the costs required for lumpsum reimbursement cannot be calculated. Products that do not meet these criteria are not considered as LPP items (Fukuda 2014).

The process of listing a medical device on the LPP after obtaining regulatory approval (CE Mark) involves several government agencies evaluating the product. The main focus is the technical evaluation conducted by the CNEDiMTS (Committee for Evaluation of Medical Devices and Technology), which consists of two aspects: "medical benefit SA evaluation" (two levels: sufficient/insufficient) and "degree of improvement/added value: ASA evaluation" (five levels: I-V, with I being the highest evaluation), which is a relative evaluation. Additional health economic evaluation will be conducted for medical devices that are expected to have a significant impact on medical insurance expenditures, but the number of products to which this applies is currently limited (Chuikyo Data 2015).

There are two types of LPPs: 1) brand name-based listing, in which products are listed by trademark or product name, and 2) generic line, in which products are listed by product type. The brand name listing is for products that are innovative, have a significant impact on healthcare financing, or have a high public health need. Some products are innovative and become generic lines over time, even if they are initially listed by brand name.

1.2.3 Coverage with Evidence Development (CED)

The so-called CED is a system to support the reimbursement listing of new products. As in other European countries, clinical evidence on efficacy is not always required at the time of regulatory

approval[v], and thus there are many cases where a product is not covered by reimbursement even after regulatory approval has been granted, thus preventing patient access to innovative medical devices. To address this situation, the CED program was introduced for medical devices and technologies in 2007 (Martelli 2016).

If the program is applied, patient access to new medical devices will be granted on an interim basis while evidence is collected to determine if reimbursement is to be given. In addition, all funds necessary for evidence collection will be covered by the insurer.

However, because the definition of innovative medical devices was unclear and medical device manufacturers themselves could not apply to the program, only two products were eligible for the program after nearly ten years. In 2015, therefore, the criteria for a product to be innovative were clarified, and the system was revised to allow medical device manufacturers themselves to apply directly to the program.

At present, the following three types of programs exist as CEDs.

1.2.3.1 PHRC (Programme Hospitalier de Recherche Clinique)

The PHRC is a program for breakthrough technologies for which no clinical evidence has been collected. In addition to regular medical fees, the government reimburses medical institutions for clinical research. Usually, the research is conducted at a single medical institution for a period of up to two years. The clinical research is led by the medical institution and, in principle, does not involve companies.

1.2.3.2 PRME (Programme de Recherche Medico-Economique)

PRME is a program for medical technologies and devices that have demonstrated efficacy and safety but lack economic data.

1.2.3.3 Forfait Innovation

This is a clinical study, with a comparison group, of a breakthrough technology for which there is a lack of evidence. The government will pay for the experimental group (new technology), the public health insurance will pay for the control group, and the companies will pay for the infrastructure (protocol development, data analysis). Companies apply for the project, and the government conducts the subject selection.

1.3 United Kingdom

The NHS is characterized by the following: (1) in principle, there is no cost-sharing for medical care; (2) all residents are eligible for benefits; (3) benefit levels are based on clinical need; (4) benefits are comprehensive health services, including prevention, treatment, and rehabilitation; and (5) most costs are covered by taxation and the system is centrally administered. Approximately 80% of the financial resources comes from taxation, and the remaining 20% comes from National Insurance, which is mainly intended to provide income security such as pensions. The National Institute for Health and Care Excellence (NICE) effectively decides benefits for new medical technologies in the NHS. The guidance issued by the NHS includes “Recommended,” “Optimized,”

---

v In May 2017, the European Medical Device Regulation (MDR) became effective as a new European medical device regulation to replace the Medical Devices Directive (MDD), requiring more clinical data on efficacy, etc. than in the past (application was scheduled for May 2020, but was postponed by one year due to the new coronavirus infection, and application began in May 2021).

"Therapeutic Use Only," and "Cost-Effective," and is intended to promote the appropriate selection of treatments, drugs, and medical devices through economic evaluations such as "cost-effectiveness." Recommended items must be made available to providers for a certain period of time. On the other hand, "Not Recommended" items are not reimbursed for service costs, with some exceptions, and thus affect the actual coverage of benefits.

1.3.1 Reimbursement for Inpatient Care

Public hospitals are organized as either NHS Trusts, which are directly responsible to the Department of Health, or NHS Foundation Trusts, which are organizationally independent of the NHS.

All public hospitals contract with Clinical Commissioning Groups (CCGs) [vi], which are made up of local clinics, to provide services and are paid according to the volume of services actually provided by the service provider based on Healthcare Resource Groups (HRGs). The DRG (Diagnosis Related Groups) rate includes medical staffing costs, and the HRG rate accounts for about 60% of hospital revenue.

1.3.2 Reimbursement for Medical Devices and Equipment

As a rule, medical devices are included in the lumpsum payment under the HRG. Pricing of medical devices is free, but hospital budgets are controlled by the CCGs. Additional payments may be made for new products that are used in larger quantities or at higher prices, based on the Innovation and Technology Tariff (ITT), etc. (see below).

1.3.3 Evaluation and Promotion Systems to Encourage Innovation

As in Germany and France, the United Kingdom has the following systems for promoting the use of new technologies and building evidence.

1.3.3.1 Commissioning through Evaluation

From among promising technologies for which clinical evidence is lacking, NHS and other public organizations will select target technologies and conduct clinical research for about three years with a maximum of 400 cases (all costs will be funded by NHS). NICE and other organizations will submit a research report on the results.

1.3.3.2 ITT (Innovation and Technology Tariff)

This system provides financial support for technologies that have evidence and are well established as technologies but are not yet sufficiently widespread. From among the technologies and devices applied for, the NHS and other public organizations will select appropriate technologies and devices, the selected technologies being treated as so-called "zero-cost models" for two years. Medical institutions can use the technology/device concerned free of charge, and the NHS pays the cost directly to the supplier.

1.3.3.3 ITP (Innovation Technology Payment)

Financial support will be provided for low-cost, high clinical utility, or highly efficient technologies that result in cost reduction. The selected technologies will be reimbursed separately

---

vi CCGs are responsible for planning, procurement, and management of non-primary, secondary, emergency, and maternal and child health care CCGs' decision-making units include local clinics, hospital-based doctors and nurses, and residents. As of 2015, there were 209 CCGs across England.

from DRGs or procured by the government for use in medical institutions. The technologies selected will be reimbursed separately from DRGs as they are used, or procured by the government for use in medical institutions.

1.3.4 Quality Improvement Measures

Since payments based on HRGs are made based solely on the amount of activity related to treatment, two reimbursement measures are also in place to achieve quality improvement (Matsumoto (2015)).

One is the Commissioning for Quality and Innovation (CQUIN), introduced in 2009, which pays for the achievement of quality improvement targets. CQUIN payments are limited to a maximum of 2.5% of the normal fee payment made to hospitals (NHS England, 2016).

The second is the introduction of the Best Practice Tariff, which began in 2010. This is a system that rewards high-quality, cost-effective medical practices. Payments based on the Best Practice Tariff are applied when treatment for specific diseases, such as stroke, cataracts, and hip fractures, is provided according to the path recommended as best practice (Hori, 2016:136).

1.4 United States

There is no public health care coverage system for the entire population. There are two public health care systems: Medicare, which covers the elderly over 65 years old and the disabled, and Medicaid, which covers low-income individuals who meet certain conditions. In 2014, the government began requiring people to purchase health care insurance, and the government has been working to reduce the number of uninsured people by expanding the number of people covered by private insurance and Medicaid. Since 2015, companies with 50 or more employees have been required to offer health insurance to their employees, and most of the uninsured are enrolled in insurance plans through company benefits and other means.

1.4.1 Reimbursement for Inpatient Care

The lumpsum reimbursement system based on DRGs, which was introduced in 1983 and pioneered worldwide, is still the basis of reimbursement for inpatient care in the United States under Medicare. After the introduction of DRGs, as the shift of inpatient care to outpatient facilities and the collaboration with facilities with acute functions progressed, various additions, subtractions, and revisions were introduced, and the overall system is sometimes referred to collectively as the Hospital Inpatient Prospective Payment System (IPPS).

1.4.2 Reimbursement for Medical Devices and Equipment

Reimbursement for medical devices and equipment is generally included in the DRG/PPS (Diagnosis Related Groups/Prospective Payment System). With new products approved by the FDA (Food and Drug Administration), a new DRG code may be assigned as a result of the submission of various types of evidence, but otherwise payment is made under the existing category.

For new products, companies can increase the selling price to healthcare providers even if they are paid under existing categories; the DRG payment amount is reviewed annually based on cost data for the past several years, but it takes time for this price increase to be reflected in the DRG payment amount, and thus the so-called “payment-lag” occurs. To eliminate the lag, medical institutions may receive additional payments through the NTAP (see below).

To obtain a DRG code for a medical device that requires a completely new procedure, it is first necessary to obtain a Current Procedure Terminology (CPT) code, which is managed and copyrighted

by the American Medical Association (AMA) and is assigned to all services that a healthcare provider may provide to a patient. The CPT code must be included in the claim.

Private insurance plans generally provide their own benefits separately from public health insurance plans such as Medicare, and the methods and amounts of such benefits vary widely.

1.4.3 Innovation Evaluation and Promotion System - NTAP (New Technology Add-on Payment)

NTAP is a program that provides additional benefits to DRGs for a certain period of time for new technologies (medical devices and drugs) with clear clinical usefulness, although the existing DRG payment amount is insufficient.

If NTAP is approved based on the company's application, the medical institution will be paid the lesser of the following amounts for the use of such products.

(1) 50% of the difference between the (original) DRG payment and the total medical cost of the device in question

(2) 50% of the cost of such device

For example, if the original DRG is 1,000,000 yen and the total medical cost (one hospitalization) with the new medical device is 1,500,000 yen, and the cost of the medical device is 600,000 yen, then 1) 50% of the difference between 1,500,000 yen and 1,000,000 yen, which is "250,000 yen" and 2) 50% of 600,000 yen, which is "300,000 yen", would in this example result in 250,000 yen being paid to the medical institution as additional benefits under NTAP.

As noted above, the NTAP will end when the cost of new technology (new medical devices) is reflected in the DRG payment, although the DRG payment amount will be reviewed annually based on cost data for the past several years, including the cost of medical devices.[vii]

1.5 Australia

Australia's health care coverage system combines the federal government's Medicare system with private insurance (about 50% of the population is covered by private health insurance). Medicare covers all citizens and provides universal coverage through a tax system. At the same time, private medical insurance and private medical services are widely used in the country to achieve both "universality," "choice," and "amenity" for users. There is no co-payment for hospital and doctor fees in public hospitals with public insurance, but there is a co-payment for patients with private insurance in public hospitals and private hospitals.

1.5.1 Reimbursement for Inpatient Care

In Australia, Diagnosis Related Groups (DRGs) are used for acute inpatient care, and the Australian Refined DRG (ARDRG), the Australian version of DRGs, is used for budget allocation from state governments to public hospitals.

1.5.2 Reimbursement System for Medical Devices

There are two types of medical devices: Those that are included in the Protheses List (PL) and for which a published price is set, and those that are covered by technical fee. PLs can be (1) surgically implanted in a patient for the purpose of either replacing a physical site or adjusting a pathological process, or (2) essential for the implantation of a specific product and disposable. In principle, medical devices for examination purposes and non-implantable medical devices are paid

---

vii Whether or not all products approved by the FDA as breakthrough medical devices (breakthrough devices) should be covered by the NTAP is being discussed.

for on a lumpsum basis.

There are two types of PLs: No-gap devices with zero patient cost and gap-permitted devices that require patient out-of-pocket.

The Australian Private Medical Insurance Act requires private medical insurance companies to pay mandatory benefits, along with doctor fees, for certain medical devices used in the course of treatment covered by Medicare benefits in hospitals.

When listed in the PL, the cost of the devices is paid to the medical institution, thus allowing the medical institution to use those devices without financial considerations. For example, pacemakers and ICDs are listed in the PL, but catheters for ablation therapy are not. Also, coronary stents are listed in the PL, but pressure wires are not.

In principle, implantable products are listed in the PL and thus treated as such, but the introduction of pressure wires has been delayed, especially in municipal hospitals, because medical institutions must bear the cost of these products, even though they are considered important for promoting the proper use of coronary stents (Griffin 2015).

2 Differences between the above five foreign countries and the Japanese system, and implications for Japan

2.1 Individual Reimbursement or Lumpsum Payment for Medical Devices/Equipment

First, let us consider whether reimbursement prices are set individually for medical device and equipment, or whether they are reimbursed as part of a lumpsum payment of a single hospitalization, as in DRG. As we have seen, Germany, the UK, and the US have lumpsum reimbursement, while France and Australia have reimbursement prices set for some medical devices and equipment. In Japan, as in France and Australia, some medical devices and materials have their own reimbursement price as Specified Insured Medical devices.

The pros and cons of each system are considered below.

2.1.1 Pros and Cons of Having Reimbursement Prices Set for the Medical Devices and Materials Themselves

The first advantage is that medical institutions do not lose money financially as long as they purchase the product at that price (or lower), and can in principle use the product they need clinically and in the amount they need without worrying about economic aspects (however, limits may be set on the applicable target, number of uses, etc.).

Furthermore, when a manufacturing and marketing approval is obtained for a breakthrough product, a higher reimbursement price may be set than for conventional products. In such cases, it is interpreted that the government has officially recognized the high value of the product, which has advantages for medical device companies, such as making negotiations with medical institutions easier.

On the other hand, if a product among newly approved products represents an improvement in ease of use for the healthcare provider, a smaller product, or a minor improvement in product performance, the new reimbursement price will not necessarily reflect the characteristics of the individual product and may be the same as the reimbursement price for the existing product category. This is one of the disadvantages[viii].

viii In the case of Japan's STM reimbursement system, each price revision is accompanied by a price reduction in relation to prevailing or foreign prices, which is sometimes seen as a disadvantage of the system for companies.

In general, the majority of medical device developments consist of a series of small incremental improvements. If these incremental improvements are not adequately evaluated through reimbursement prices and do not result in increased revenues for companies, then R&D costs will not be fully covered, reducing development incentives for companies. This may delay the emergence of new technological innovations in the medical field and may hinder the improvement of the quality of care.

2.1.2 Pros and Cons of Lumpsum Payment

One advantage of lumpsum payment is that it is relatively easy for payers (insurers) to control medical costs. On the other hand, for medical institutions, costs may exceed reimbursement prices in terms of individual patients, and this may restrain the use of new medical devices and equipment.

For companies, the reimbursement price of the lumpsum payment includes all hospitalization, labor, and drug costs, which leaves room for raising the price of improved products and creates an incentive to actively introduce improved products. This is the reverse of the disadvantage of having reimbursement prices set for the medical devices and materials themselves, as described above.

On the other hand, when the price of an improved product is raised, the cost portion of the lumpsum payment increases for the purchasing medical institution, which puts pressure on profits, making it difficult to actively purchase the improved product even if it is clinically useful.

In order to solve these problems, a reimbursement price surcharge system for a certain period of time, described in the next section, exists in Germany, the UK, and the US, where lumpsum payments are made.

2.2 Reimbursement Add-on Program for a Certain Period of Time

In the lumpsum payment systems in Germany, the UK, and the US using DRGs, etc., the government periodically surveys the costs incurred by medical institutions and reflects them in the amount of the lumpsum payment. However, there is a time lag in this reflection, and when the purchase price of new medical equipment increases, medical institutions suffer financially in the meantime.

The NUB in Germany, ITT in the UK, and NTAP in the US have been introduced to solve the problems of these lumpsum payment systems. Systems similar to these do not exist in France and Australia, where reimbursement prices are given for each medical device and material.

2.3 Clinical Evidence Collection Support System

Many countries have introduced systems to promote the collection of clinical evidence in order to make appropriate decisions on whether or not to provide reimbursement.

Especially in Europe, under the CE Mark, regulatory approval was granted with less clinical data than in Japan and the U.S., and there were many products that were not reimbursed even after obtaining approval.

Therefore, a system has emerged in which the government provides incentives to medical institutions and companies in various ways to promote the collection of clinical evidence.

In a survey of 22 European countries conducted by Federici (2021), seven countries had programs to support the collection of clinical evidence, with varying methods.

The applicants were “companies and medical institutions” in France, the Netherlands, and Switzerland, and “government and public institutions” in Belgium, the United Kingdom, Germany, and Spain.

As for the funding, in most cases, the costs related to the provision of medical care itself were paid by the public health care system, but the operational costs of creating research protocols, data collection, and analysis were in some cases covered by public funds (Belgium, Spain, and the United Kingdom) and in other cases partially or entirely by the system applicant (France, Germany, and Australia).

Among the five countries that have been discussed so far, the Erprobungsstudie system in Germany, the PHRC and the Forfait innovation system in France, and the Commissioning through Evaluation system in the UK are considered to be clinical evidence collection support systems.

Japan's Advanced Medicine (Senshin Iryo) is similar to the European system in some respects, but the applicant is the medical institution, the cost of the medical care itself is borne by the public medical insurance and the patient, and the medical institution bears the operational costs of creating research protocols, collecting data, and analyzing the data.

Another difference between the systems in European countries and Japan is that most of the systems in European countries cover items that have been approved by the regulatory agencies, while in Japan, although Advanced Medicine A covers items that have been approved by regulatory agencies as in Europe[ix], Advanced Medicine B covers items that have not been approved.

In Japan, medical technologies (pharmaceuticals, medical devices, etc.) that have been approved by regulatory agencies are, in almost all cases, reimbursed by National Health Insurance. In particular, the rule for pharmaceuticals is that they must be covered by insurance within two to three months of approval, with the exception of certain items for preventive purposes. In the case of medical devices, there are some approved products that are not listed on the insurance list, but even so, those that are not reimbursed are the exception. Therefore, it can be said that advanced medicine B, which is not regulatorily approved, is positioned somewhat differently from non-approved items in European countries.

2.4 Implications for Japan

We have reviewed medical device reimbursement systems in other countries and examined their characteristics. Let us now consider the implications for the Japanese system in terms of two points that were identified as differences from the Japanese system: "reimbursement evaluation of product improvements" and "handling of cases in which clinical data are insufficient."

2.4.1 Reimbursement Evaluation of Product Improvements

As discussed above, "improvement" is key to medical device product development. While there are some cases where a completely different and revolutionary product is created (Goto, 2018), in most cases, minor incremental improvements improve the quality of the product, and thereby the outcomes.

In order to continuously encourage such improvements, it is extremely important to evaluate them. To address this issue, Japan's reimbursement system established an "additional improvement fee" in 2008.

However, the number of improvement additions applied for peaked in 2012-2014 and has been declining (Table 2).

ix Unapproved *in vitro* diagnostic products are also included in Advanced Medicine A.

Table 2: Number of Improvement Additions

Period	Number of improvement additions
2008-2010	6
2010-2012	8
2012-2014	32
2014-2016	14
2016-2018	7
2018-2021	10
Total	67

While the possibility that the actual number of product introductions corresponding to improvement additions may have fluctuated cannot be ruled out, as Tamura et al. (2019) point out, it is also possible that there has been a change in the administrative authorities' approach to the evaluation of improvements. Starting in 2018, a "time-limited improvement addition" (B3) was created, but this addition was granted in only one case, and it is difficult to say that it is functioning adequately at present.

In contrast, in other countries, there is an aspect in which consideration is given to the improvement of medical devices. In other words, in order to make it easier for medical institutions to purchase improved medical equipment when the purchase price increases, a system is established whereby the reimbursement price is increased until the amount of the lumpsum payment increases, including the increased cost of the medical device.

The medical device industry has been requesting revisions to time-limited improvements (B3), and including such improvements, and further incentives for medical device companies to make improvements, would be an important element in terms of capturing advances in medical technology and improving the quality of medical care.

2.4.2 Lack of clinical data

In other countries, especially in Europe, the hurdles for regulatory approval have been relatively low in the past, and various systems have been established to accumulate the clinical data necessary to make decisions on reimbursement.

In Japan, as mentioned above, there is also a system of Advanced Medicine, but its positioning is somewhat different from that of Europe. In terms of the accumulation of clinical data after approval, Japan established a "challenge application" system in 2018, under which evidence is collected and submitted after the product is placed on the reimbursement list and reevaluated. This means that if all the characteristics of a medical device cannot be fully evaluated at the time of reimbursement coverage, even if the device is insured at an undervalued reimbursement price, for the time being, there is a pathway for it to be appropriately evaluated later on.

In Japan, "device lag"[x] became a social problem in the late 2000s, and the need for expedited regulatory approval was called for. It is good news for the medical community and patients that medical devices embodying new technologies are approved more quickly and that an environment is created for their widespread use. On the other hand, it is also true that if regulatory approval is accelerated, it will be difficult to prepare and evaluate sufficient data to accurately demonstrate the value of the technology. Challenge applications are effective in reconciling these two contradictory situations. The establishment of such a system is highly significant because it is sometimes more difficult to secure

x Device lag refers to the fact that medical devices that can be used overseas cannot be used in Japan.

clinical data for some medical devices than in the past due to the limitation of the indications for which the device is recommended and other factors. Since the establishment of this system, five challenge applications have already been approved, and awareness of the need for this system is growing.

The compatibility between rapid introduction of technology into society and appropriate evaluation with sufficient data is a common challenge, regardless of the insurance system's treatment, whether it be lumpsum or individual evaluation. This challenge application system, which was only for STM when it was first introduced, but was also applied to Non-STM (technical fees) from 2022.

Finally, in Europe and the US, as in Japan, there is a growing demand for value-based pricing in response to rising healthcare costs (Sorenson et al. (2013)). In line with such trends, for example, in the EU countries, it is reported that the number of cases in which Patient-Reported Outcome Measures (PROMs) are added to the approval review process, in addition to the conventional efficacy and safety measures, is increasing.[xi] (Miklós et al. (2019). This is true not only in EU countries, but also in the US, where studies using PROMs increased by more than 500% between 2009 and 2015 (ibid.) The increased use of PROMs in EU countries has been attributed to public procurement guidelines issued in 2014 (Directive 2014/24/EU). In the procurement of medical devices, more emphasis is being placed on aspects such as quality, life cycle costs, cost-effectiveness, and social benefits, in addition to the traditional price advantage. In Japan, it is expected that the trend toward evaluating medical devices based on the value they bring will become even stronger, and a more multifaceted value evaluation method utilizing patient-reported outcomes, etc., must be established.

References

Carbonneil C (2017) "New French Coverage with Evidence Development for Innovative Medical Devices: Improvements and Unresolved Issues." Value Health 20:178-179

Federici C, Reckers-Droog V, Ciani O, Dams F, Grigore B, Kaló Z, Kovács S, Shatrov K, Brouwer W, and Drummond M (2021) "Coverage with evidence development schemes for medical devices in Europe: characteristics and challenges," *European Journal of Health Economics*, Jun 12

Fukuda T (2014), "Research and Study on Medical and Economic Evaluation of Medical Care and Drugs, etc.: Focusing on Efforts in France", Report of KENPOREN, Health Security General Policy Research and Survey Fund Project

Goto R, et al. (2018), "One Medical Device Caused a Revolution in the Treatment of Valvular Heart Disease (A-C) - Transcatheter Aortic Valve Therapy (TAVI)", Keio University Business School (in Japanese)

Iwama Y (2016), "Trends in the Medical Reimbursement System in Germany," Kenporen Overseas Medical Security, No. 111:1-11 (in Japanese)

Japan External Trade Organization (JETRO) New York Office (2021), "Overview of the Health Insurance System in the United States.

Kato T and Matsumoto Y (2015), "Medical System Reform in France," in Katsuaki Matsumoto (ed.), Medical System Reform: Comparative Analysis of Germany, France and the UK and Implications for Japan JUNPOSHA (Chapter 2) (in Japanese)

Kato T (ed.) (2016), Medical Reimbursement Around the World, HORITSU BUNKASHA. (in Japanese)

xi In clinical studies selected by device category between 1998 and 2018, 65% in the UK and 52% in Germany included PROMs.

Katagiri Y and Shirase Y (2015), "Health Care System Reform in the United Kingdom," in Matsumoto K (ed.), Health Care System Reform: A Comparative Analysis of Germany, France, and the United Kingdom and Implications for Japan, JUNPOSHA (Chapter 3) (in Japanese)

Ministry of Health, Labour and Welfare (2015) "2014 Survey on Overseas Status of Insured Medical devices, etc.", Chuikyo Medical devices System Subcommittee (October 14, 2015). (in Japanese)

Matsumoto K (2015), "Health Care System Reform in Germany," in Matsumoto K (ed.), Health Care System Reform: Comparative Analysis of Germany, France, and the United Kingdom and Implications for Japan, JUNPOSHA (Chapter 1)

Martelli N, et al. (2016) "New French Coverage with Evidence Development for Innovative Medical Devices: Improvements and Unresolved Issues," *Value Health*, 19:17-9.

Miklós Weszl, Fanni Rencz and Valentin Brodszky (2019) "Is the trend of increasing use of patient-reported outcome measures in medical device studies the sign of a shift towards value-based purchasing in Europe?", *The European Journal of Health Economics*, 20 (Suppl 1): 133-140.

Mossialos E, Djordjevic A, Osborn R and Sarnak D (2020) "International Profiles of Health Care Systems,"
https://www.researchgate.net/publication/347011106_International_Profiles_of_Health_Care_Systems_2020)

MTRC Research Paper (2018) Innovative payment schemes for medical technologies and in-vitro diagnostic tests

Office of Life Sciences: NHS (2019) MedTech landscape review.

Sarah Griffin (2015) "Reimbursement Unraveled: Australia's schizophrenic device coverage system"
(https://www.medtech.org/assets/REIMBURSEMENT-UNRAVELLED-Australia-1505.pdf)

Sorenson C, Drummond M and Burns LR (2013) "Evolving reimbursement and pricing policies for devices in Europe and the United States should encourage greater value," *Health Affairs (Millwood)*.32 (4):788-96.

Tamura M, Nakano S, Sugahara T (2019) "Reimbursement pricing for new medical devices in Japan: is the evaluation of innovation appropriate?", Int J Health Plann Mgmt. 34 (2):583-593

Tanaka S (2019) "Germany's DRG Comprehensive Reimbursement System," KENPOREN KAIGAI IRYHOSHO, No. 123:1-11 (in Japanese)

Journal of International Economic Studies (2023), No.37, 39–54

Balancing Medical Equipment Costs with Public Finances

Kazumasa Oguro
Professor, Hosei University

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.

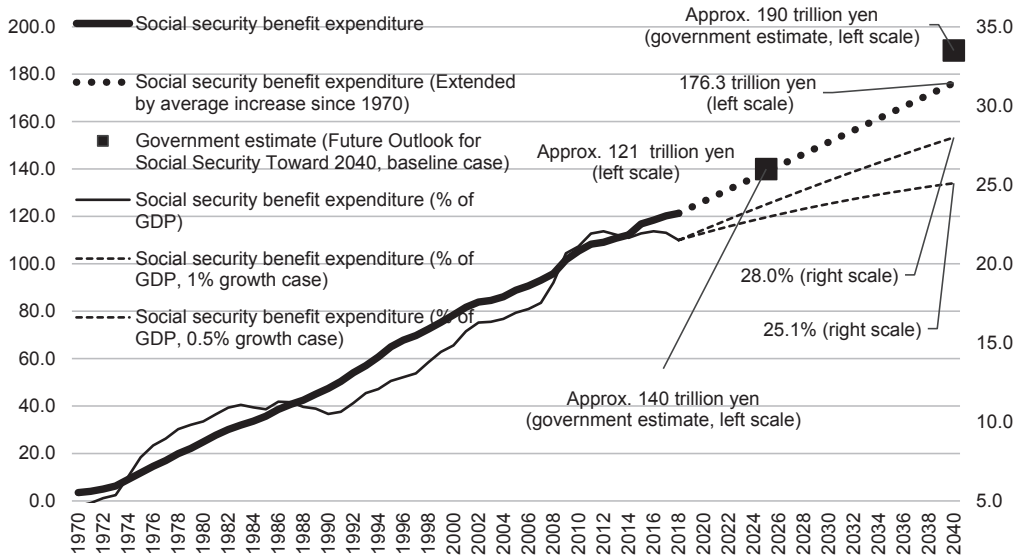
2. Current State of Japan's Finances

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.

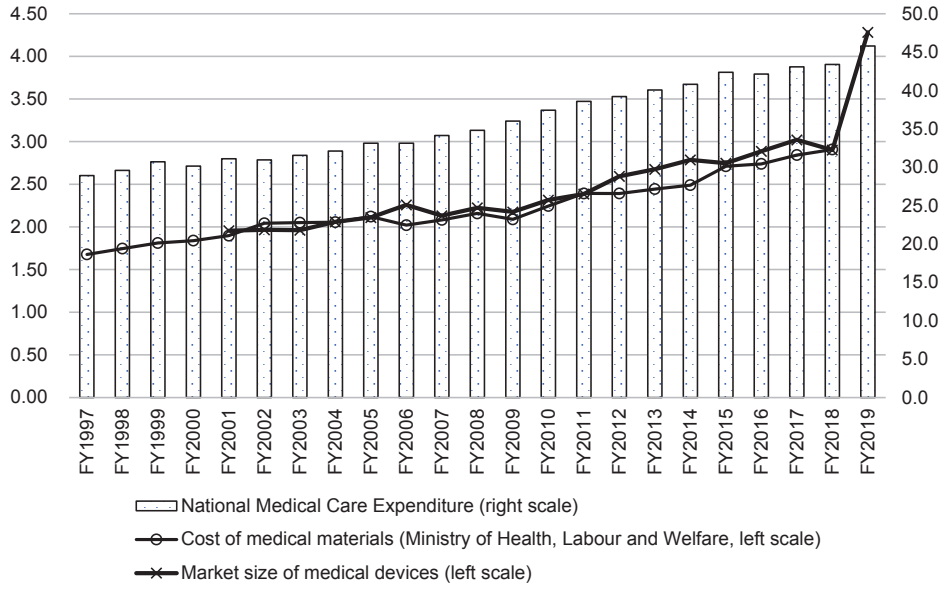
The above is the scope and definition of medical devices. The main reason that it is difficult to estimate the total amount accounted for by medical devices in NHI expenditure is that there are such categories as A1 (comprehensive) and A2 (specifically comprehensive) under the rules for calculating reimbursement 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.

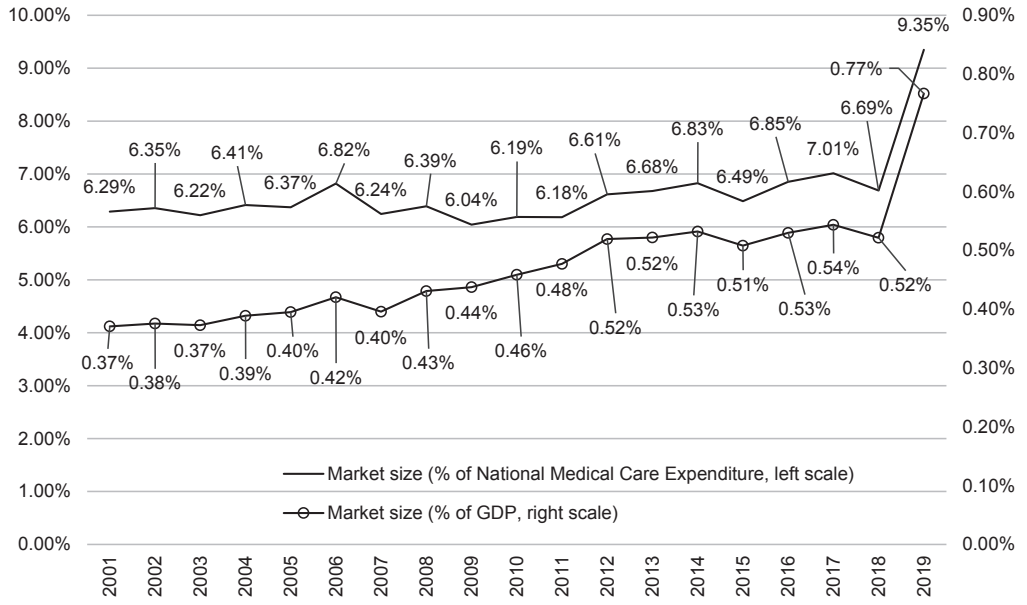
The second reason is that the survey methodology employed by "Statistics of Production by Pharmaceutical Industry" was fundamentally changed in January 2019, and "increases and decreases

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

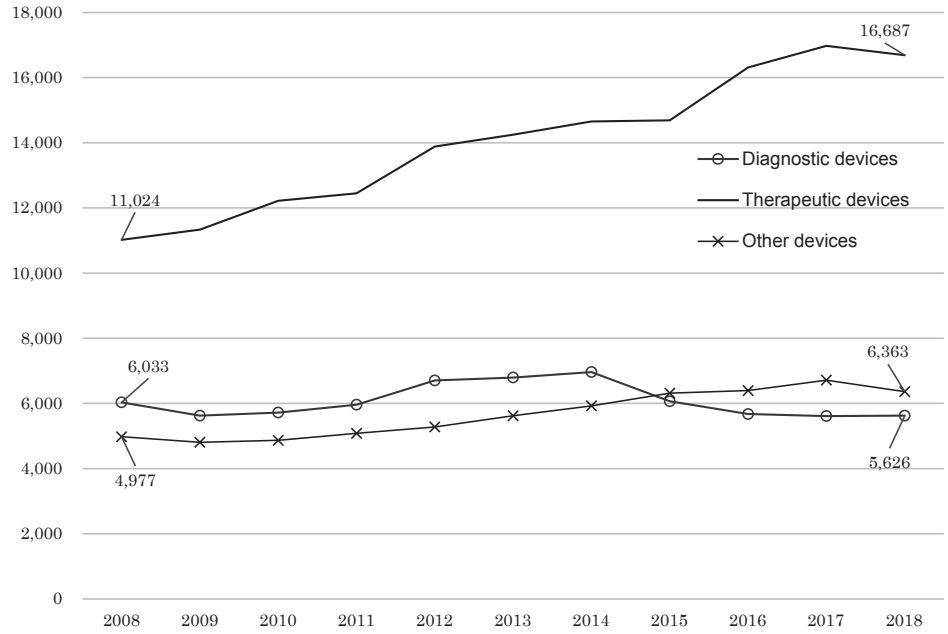
grown slightly faster than the nominal GDP growth rate, although it should be noted that there are some statistical problems, as already mentioned.

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)

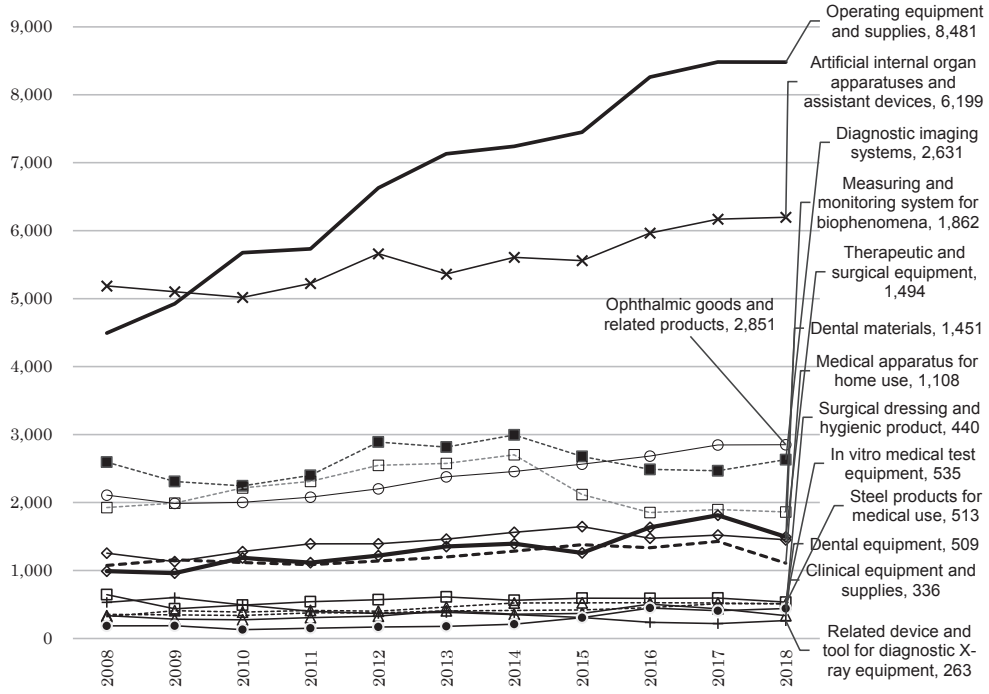


Source: Compiled by the author from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan.

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)



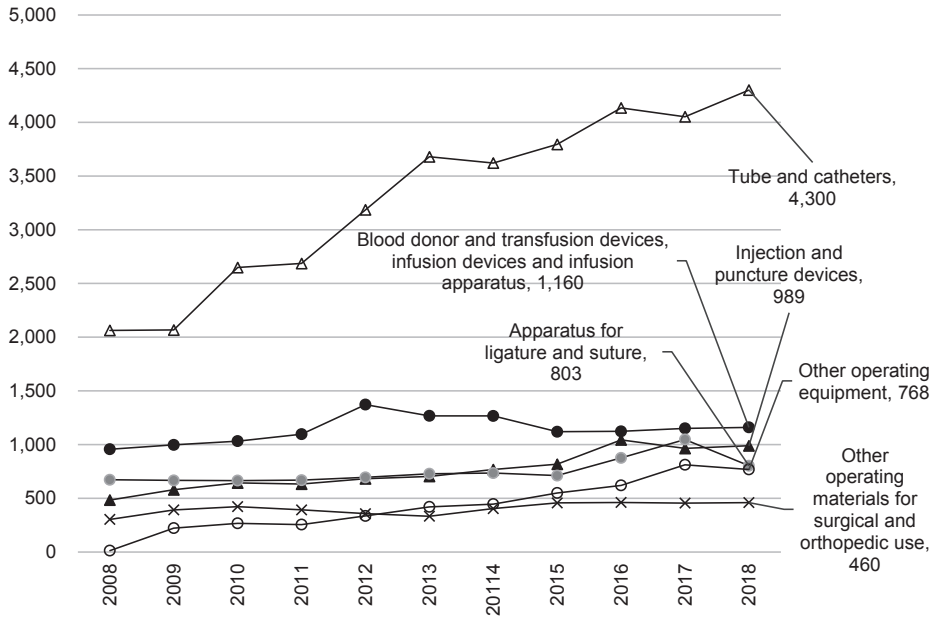
Source: Compiled by the author from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan.

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

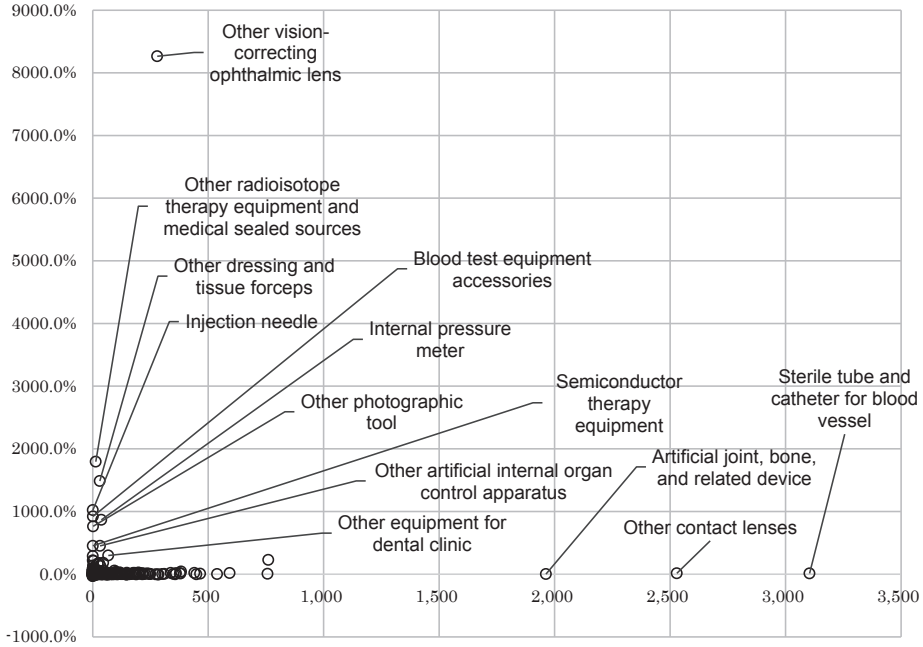


Source: Compiled by the author from "Statistics of Production by Pharmaceutical Industry," Ministry of Health, Labour and Welfare, Japan.

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

Journal of International Economic Studies (2023), No.37, 55–67

Challenges and Prospects in the Medical Device Industry -Heading toward a Leading Japanese Industry-

Takuma Sugahara
Hosei University Faculty of Economics

Abstract

This paper examines the challenges and prospects for further development of the medical device industry, which is becoming increasingly important as an industry that leads innovation and contributes to medical care. Issues include insufficient understanding of the industry as a whole due to the wide range of medical devices, inadequate insurance reimbursement systems to evaluate new innovations, and a shortage of database development and utilization. There are still insufficient industrial promotion measures, and how to ensure the balance between the sustainability of the medical insurance system and the reimbursement of medical equipment with the aging of the population and the rapid decline in the working generation is also of critical importance. In the future, based on these issues, it is necessary to promote product development from the patient's perspective under an insurance reimbursement system that can appropriately evaluate innovation, and to achieve both further international expansion and a stable domestic supply.

Keywords: medical devices, medical insurance, innovation, SaMD: software as a medical device, patient-oriented development

JEL classification: **I28, K23, L20, L51**

1. Introduction

In Japan, the efforts of medical professionals and the introduction of new medical technology have made progress in dealing with and overcoming diseases that were once difficult to treat, thereby extending people's life expectancy and improving their quality of life. As evidenced by the fact that during the coronavirus pandemic many critically ill patients were saved by extracorporeal membrane oxygenation (ECMO), the development and introduction of new medical devices is a matter of great concern not only for patients suffering from disease but also for society as a whole.

When the medical device industry is viewed as a single industry, the current market size is about three trillion yen, of which about one-third is covered by medical insurance, evaluated individually as specified insurance medical materials, the remainder being evaluated comprehensively as medical fees, technical fees, etc. In recent years, along with the advancement of digitization, medical devices themselves have become more sophisticated, and the emergence of programmed medical devices (SaMD: Software as a Medical Device) has led to developments that transcend the traditional "market boundaries" of mono-centered products. In addition to the adjacent pharmaceutical industry, there are also active moves to seek new entrants from the electronics and materials

industries. The boundaries of medical devices are thus spreading, many devices combining intellectual property and incorporating sophisticated technologies. As a knowledge-intensive industry, the medical device industry is expected to grow as an internationally competitive industry that will lead Japan's innovation in the future.

The Cabinet approved the "Basic Plan for the Promotion of Research, Development and Dissemination of Medical Devices to Improve the Quality of Medical Devices to be Received by the Public" (hereinafter referred to as the "Basic Plan" and abbreviated as the "Act on the Promotion of Medical Devices") in May 2016 as the first basic plan specializing in medical device policy, and the government has been implementing and promoting various measures ranging from research and development to commercialization and international deployment. The report presented the current recognition that the international presence of domestic medical device companies is relatively low, that the trade balance deficit rate in medical devices is significantly higher than that for Japan's overall trade, and that further new development and overseas expansion are necessary due to the insufficient entry of Japanese companies. In addition, the following were cited as issues: strengthening international competitiveness by field, development of advanced and innovative technologies through medical-industrial collaboration, and cooperation with medical institutions[1].

On the other hand, what are the issues that arise after product development? As many medical devices are applied and used in insurance practice, there has been a constant debate on how to capture the value they provide, how to evaluate them appropriately to promote innovation, and how to review approvals and reimburse insurance. In recent years, legislation has been enacted for the "Pioneer Examination Designation System" and the "Conditional Early Approval System." In addition, in the medical fee revision in 2030, the "Challenge Application" and the "Time-Limited Improvement Addition for Substituted Products" have been newly established. These measures are worthy of a certain evaluation as positive responses to criticism of the conventional system operation.

In view of the sharp decline in the productive age population, which supports social insurance finances with strong intergenerational dependencies, and the increasingly severe medical finances, there is a growing need to promote discussions to improve the system while taking into account the appropriate application and diffusion of effective medical devices as well as the harmonization with the medium- to long-term public finances and the sustainability of the insurance finances.

In this paper we will point out a broader range of issues that were not necessarily addressed in the discussion of the individual issues thus far and look forward to the future direction.

2. Issues Surrounding the Medical Devices Industry

2.1 Difficulty in ascertaining the actual situation of the industry

Accurate understanding of the current state of the industry is essential in considering the ideal form of the industry and system design for the future. With respect to the medical device industry, the large number and diversity of products and their distribution across traditional industrial classifications tends to obscure the boundaries of industries in reality. Similar phenomena can occur in other industries, but in the medical device industry, gauze, medical cotton, blood pressure monitors, MRI, cardiac pacemakers, and prosthetic joints are included in the same category,

1 In the "Medical Equipment/Healthcare Project (Former: All-Japan Medical Equipment Development Project)", which is an integrated project of the "Medical Research and Development Promotion Plan" based on the health and medical strategy that is progressing in parallel, strengthening the development support system through cooperation among the Ministry of Health, Labor and Welfare; the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Economy, Trade and Industry, efforts to speed up approval reviews of medical devices, human resource development, and strengthening of intellectual property are advocated.

depending on the definition. Accordingly, it is desirable that each company grasp and scrutinize the composition of the products it sells and group together with companies that have a similar composition in order to manage statistical treatment. In the cost calculation method used to determine the reimbursement price of the medical device industry, an average profit rate was calculated based on the Survey of the Medical Devices Industry in the calculation of operating profit. However, there is little reason to apply the overall average value of enterprises of different size and product composition.

Due to the difficulty of accurately apprehending the entire medical device industry from generally published statistical data, Ishikawa (2023) attempts to compile counts from sub-classifications of METI's Census of Manufactures, but delicate items such as "Manufacturing of microscopes, telescopes, etc." still remain to be resolved. Similarly, R&D expenditure, which is important for grasping the status of the medical device industry, remains an issue for accurate counting, given the fact that only a few subgroups are recorded.

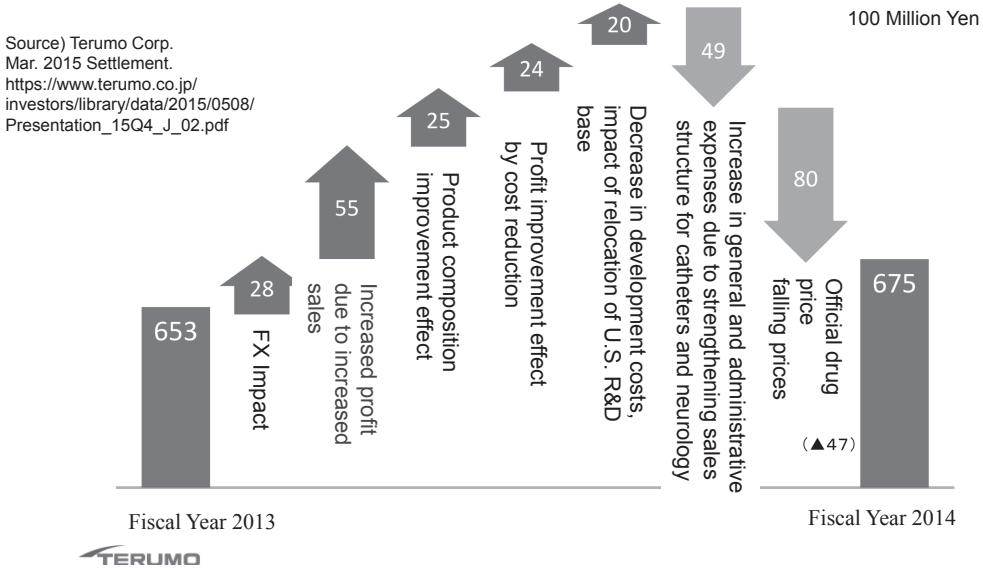
If the government wishes to improve the reimbursement system, design the system in line with the actual situation in the industry, and revise the rewards, it is necessary to develop detailed statistics that enable discussion and verification. In the future, it is desirable to develop detailed statistics on the medical device industry in cooperation with the industry and related authorities.

2.2 Issues in the reimbursement system from the viewpoint of promoting innovation[2]

In situations where many of the resources for research and development are heavily dependent on the earnings of a company's own products, the setting of material prices plays a critical role in the recovery of R&D expenditures. In a functional category (category B) system where multiple existing product brands are placed within the same frame, the price of another company's products influences the price in determining the reimbursement price of the company's products. Of course, the effect of promoting competition among products placed within the same framework can be expected. However, a mix of differentiation-oriented, technologically competitive products and pricing-oriented products may hamper healthcare outcomes and quality improvement by placing greater emphasis on prices when the incentives of medical institutions are heavily dependent on "margin gains." In addition, the autonomous pricing function that should be respected in market competition is undermined, bringing uncertainty to the company's medium- to long-term outlook and influencing the company's business execution predictability. Indeed, price revisions once every two years in such a framework have had a profound impact that would eliminate much of the large profit-making efforts that firms have made.

2 The recognition of issues in this section is also based on the organization of issues in the "Research Report on Future Medical Device Policy" by the "Study Group on Future Medical Device Policy," in which the author himself participated as a member.

Figure 1: Analysis of Changes in Operating Profit



The "Special Provisions for Functional Classification" system introduced in 2014 is designed to revise and re-calculate the price of reference materials for highly innovative products that meet certain standards, separately from other already listed products belonging to the functional category, until they are revised twice after being newly listed. Since these products are not affected by the price of the products of the same category that will be filed later, this measure can be regarded as a certain degree of improvement for the aforementioned issues.

However, this "special exception for functional category" applies to medical materials and orphan medical devices with newly established functional categories based on the addition of innovativeness or addition of usefulness (limited to supplementary premiums of 10% or more)[3]. The overall coverage is limited and does not address incremental improvements in existing products. In addition, the current rules stipulate that prices will be unified in accordance with the same functional category after two revisions have been made following the new listing. The protection of innovation in the medical device industry is still relatively fragile compared to the pharmaceutical industry, where the brand listing system for individual products is adopted, the rights of the core part of the innovation are protected by strong material patents, and the patent extension system is functioning against erosion of the patent period in the regulatory and approval examinations[4]. There is room for further consideration as to whether the special period of "two revisions" is sufficient to evaluate innovative products that acquire a certain level of premium for breakthroughs and usefulness and set new functional categories.

2.3 Infrastructure development for industrial development

In Japan, the Japan Agency for Medical Research and Development (hereinafter referred to as "AMED") was established in April 2015, and seamless research and development from basic to

3 Other applicable conditions were developed in response to public offerings made by the Ministry of Health, Labour and Welfare based on the results of the needs review committee.

4 See Sano (2012) for the impact of patent term extensions on innovation in the pharmaceutical industry.

practical application in the medical field, support for research institutes to facilitate smooth practical application of the results, and improvement of the business environment have been promoted. AMED has a budget of approximately 150 billion yen annually, which has great significance from the viewpoint of establishing a foundation for medical research and development. However, compared with the annual budget of the National Institutes of Health (NIH) in the United States, reaching about 3.5 trillion yen, it is as yet insufficient. If there is a limited amount of R&D subsidy or national R&D subsidy for medical devices, domestic companies in particular will not deny that they will be able to meet their own financial needs. In particular, AMED is expected to be further enhanced, as it may become a disadvantage in competition for product development with foreign countries.

Next, I would like to touch on the importance of establishing a large-scale national database and establishing infrastructure for wider utilization. Along with the advance of ICT in the healthcare sector, efforts are also underway for "digitization and standardization of medical information," "networking in the sharing and cooperation of medical information," and "big data creation for innovation." In 2017, the Headquarters for the Promotion of Data Health Reform, headed by the Minister of Health, Labour and Welfare, was inaugurated and discussions are being accelerated. Mentioned as future goals of the new data health reform in the future were "promotion of the effective use of databases," and "invigoration of research by private companies and researchers."

Research using medical information data in Japan has been delayed compared to the U.S. and Europe. However, with the development of medical databases, both quality and quantity have been enhanced in recent years. In addition, the National Database (NDB) has become available to private businesses since it is deemed to be in the public interest as a result of the amendments to the Health Insurance Law in 2019. NDB is Japan's largest big data collection of medical information and can be used for a wide range of purposes, including searching for medical needs, estimating the number of patients, and confirming safety and efficacy in the real world.

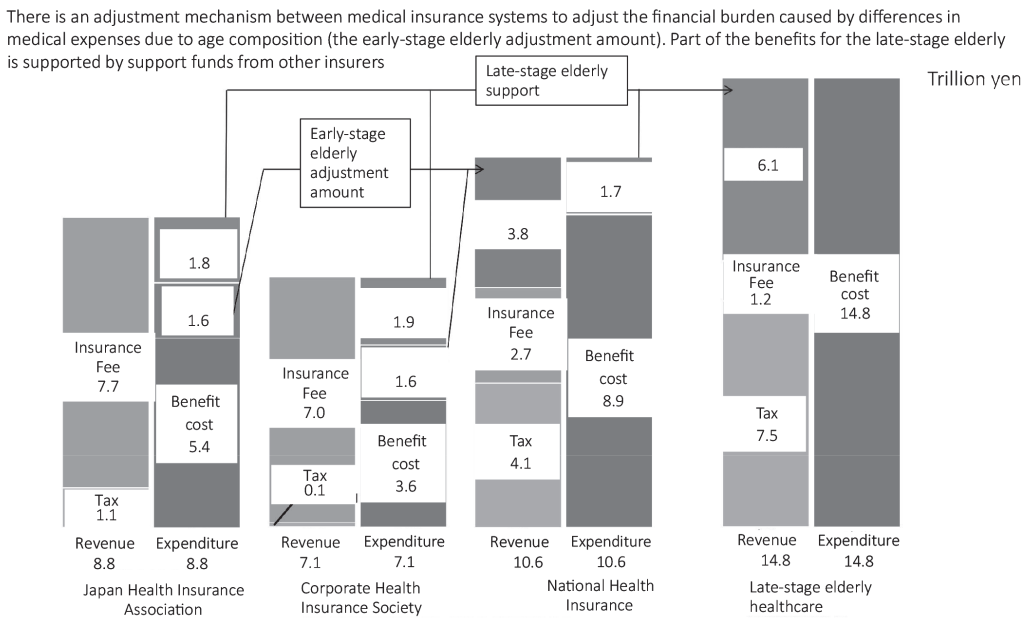
There are also large-scale databases in the health sector; MID-NET is an anonymous database operated by PMDA and held by cooperating medical institutions. Receipt data and electronic medical record data for 4.5 million patients in cooperating medical institutions (23 hospitals) are collected and constructed for anonymization and standardization (as of October 2018). The collected data can be used by the government, pharmaceutical companies, and academia for research and analysis of safety information on drugs. Primarily for the purpose of utilizing post-marketing safety monitoring and risk-benefit evaluation of drugs, it is expected that the database will be utilized for the development and evaluation of medical devices in the future. However, the current data usage fee, for example, exceeds 40 million yen per product in the post-marketing surveillance of drugs, and the number of users is limited due to the cost burden. Efforts should be made to open up the way to widespread use of the database by medical ventures with limited financial resources.

2.4 Harmonization of fiscal policy, sustainability of the health insurance system, and industrial promotion

As the baby boomer generation is becoming older, the aging rate in Japan is now about 30%. On the other hand, the decline in the birthrate has not stopped, and the declining trend in the youth population has yet to be halted. If we divide the current population of people aged 65 or older by the working-age population of people aged 15-64, we can say that two people among the working generations support one elderly person. Considering that in 1970 one elderly person was supported by approximately ten persons and in 2000 by approximately four persons, it can be seen that Japan's declining birthrate and aging population are proceeding at an extremely rapid pace. On the other hand, it is known that medical expenses per elderly person aged 75 or older are about five times

higher than medical expenses per person aged 64 or younger. While the growth in medical expenses per elderly person is under good control at present, the "natural increase" that accompanies the aging of society is unlikely to be stemmed. This is a major concern for ensuring the sustainability of Japan's "generation-dependent" social security system, including the medical insurance system, which is characterized by the support of the elderly generation. Looking at Figure 2, it can be seen that a considerably high proportion of contributions have been made to support the medical care of the elderly from the insurers of the working generation as part of the contribution to the early-stage elderly and support for the late-stage elderly.

Figure 2: Overview of Finance Status by Insurance System (2017)



Source: 132nd Social Security Council Health Insurance Division

In terms of the relationship between the burden and the benefit, there is a large gap between the current elderly and the working generation. At present, when the baby boomer generation, which is at the core of the productive age population, joins the elderly, the productive age population that supports the elderly will further shrink. Therefore, it will be even more difficult to sustain the health insurance finances while maintaining the current burden and benefit level. In any case, in order to establish a sustainable health insurance system in the future, it will be necessary to increase the burden of medical expenses in line with the increase in medical expenses, or to make the benefits more appropriate. The amount of reimbursement for medical devices is also a component of national medical expenditures, and while expecting to play a leading role in leading the nation's economic growth in the future, it will also be necessary to consider measures to rationalize benefits for medical devices at the same time.

Economic analyses that test cost-effectiveness provide a valuable basis for choosing new healthcare technologies and are expected to continue to be used in the future as fiscal constraints become stronger. In addition, the scope of pharmaceutical approval and insurance coverage to confirm the efficacy and safety of medical devices may differ between the two (approval and insurance coverage). In such cases where the pharmaceutical affairs are wide and the insurance

coverage is narrow, the inclusion of the portion not covered by insurance, as covered by the combined medical care expense system, may increase the choice of patients while avoiding the burden on the medical insurance system. In addition, if there are cases in which, as a result of economic analysis, insurance coverage is postponed because it does not match cost-effectiveness, while the efficacy and safety are maintained, insurance coverage up to a certain threshold will be allowed, and the portion exceeding that threshold will be subject to non-insurance combined medical treatment. Thus, consideration will be given to insurance finances, the choice of patients will be expanded, and institutional arrangements will be made to balance the viewpoints of industrial promotion through the introduction of technology into society[5].

3. Future Outlook - Direction and Response to Leading Industries Trusted by the Public

The Basic Plan, based on the Act on the Promotion of Medical Devices, lists five items that should be implemented comprehensively and systematically: 1. promotion of research and development of advanced medical devices; 2. measures for cooperation beyond the previous framework of medical device developers; 3. ensuring the approval system and proper use of medical devices; 4. promotion of export of medical devices and international cooperation and deployment; 5. other important issues (matters necessary to promote policies for the promotion of research and development and dissemination of medical devices comprehensively and systematically). Each item lists and organizes "matters to be considered for realization" and "specific measures for realization." All these descriptions are appropriate, and although there are differences in the progress of each measure, these are all progressing in the direction indicated. Based on this, we will touch on issues that need to be considered from a broader perspective, including those that were not mentioned in the Basic Plan.

3.1 Development and evaluation from the patient's perspective

As mentioned in the section on Measures for Utilizing the Non-insured Concomitant Medical Expense System, the evaluation viewpoint when obtaining regulatory approval and the evaluation viewpoint when applying insurance are very different. Evaluation at the time of regulatory approval is based on whether the device has the indications, performance, and safety related to the application. On the other hand, the evaluation at the time of listing in insurance is the extent to which the benefits (usefulness) are extended to patients receiving benefits associated with the use of the device. Needless to say, the scale and scope of use will also be problematic in light of the impact on insurance finances as a whole and the burden on the people.

Compared to regulatory approvals, which emphasize technical evaluation, evaluation at the time of insurance listings focuses on clinical usefulness and outcomes, such as evaluation of supplementary premiums. The evaluation of usefulness can be summarized along three axes: 1) a technology that makes it possible to do something new that was impossible in the prior art, 2) a technology that expands the application of the prior art, and 3) a technology that reduces the burden on patients and medical professionals regarding the application of the prior art. Regardless of the axis, it is crucial how the endpoints and outputs used in the study data are linked to and persuasively explained to the true end-point patient outcomes. In some cases, nonclinical results do not necessarily

5 On the other hand, the utilization of such a system of medical expenses combined with noninsured medical expenses can naturally be criticized for causing a stratification of the medical treatment that can be received, and thus careful consideration and discussion are necessary.

correlate with clinical efficacy, and in some cases, clinical efficacy is not sufficiently effective under general conditions that differ from those of the study site, or even if it is effective, it may remain small. In this regard, it is necessary for those who are strongly aware of the outcomes from a more accurate patient perspective to make further efforts in the framework of "challenge application," "evaluation and medical treatment," and "advanced medical care," and who are involved in the clarification and evaluation of the outcomes. In such cases, not only objective evaluation by a specialist in the patient's condition image, but also collection of and reflection on subjective evaluation by the patient should be considered in the future, even though there are concerns about fluctuations due to individual differences.

In recent years, there has been a worldwide movement to achieve patient-oriented healthcare by supporting and respecting patients' self-decisions about treatment through adequate information provision, premised on the existence of information asymmetries with health professionals. As for medical devices used for diagnosis and treatment, it is considered best to discuss how to provide accurate and easy-to-understand information so that not only medical professionals but also patients themselves can obtain sufficient information and make a self-determination as to whether or not to use the devices.

There is a similar debate about the multifaceted value of medical devices, such as improving labor productivity and quality of life of patients and their families, and the reflection of their value in pharmaceutical products. However, it is necessary to consider that the value of each function is far more diverse in medical devices.

3.2 A reimbursement system that is highly predictable and rewards innovation

Medical devices are subject to various regulations in all phases, from development to approval, manufacturing, and marketing. In the modern era, where corporate activities have diversified in relation to society, it is common for any industry to be affected by some kind of regulation, but the medical device industry, along with the pharmaceutical industry, is characterized by regulatory influences in almost all of its business activities. In the medical device industry, the reimbursement price is "publicly determined" and at the same time it is the actual upper limit of the transaction price. In the functional listing, the influence of the price change of "other company" products classified in the same category is reflected in the company's new official price. This is a major difference from the price formation process of ordinary transactions. In addition, we pointed out in 2.2 of the previous section the issues related to price formation brought about by such systems, including the decline in predictability in business activities.

The brand listing system adopted in the Official Pricing of Pharmaceuticals is expected to have a stronger effect on product improvement and improvement in terms of individual product evaluation. On the other hand, compared to drugs, the number of medical devices is extremely large and the content diverse. Therefore, the difficulty of adopting a brand-specific listing system for medical devices can be understood to a certain extent from the viewpoint of regulatory costs and administrative costs[6].

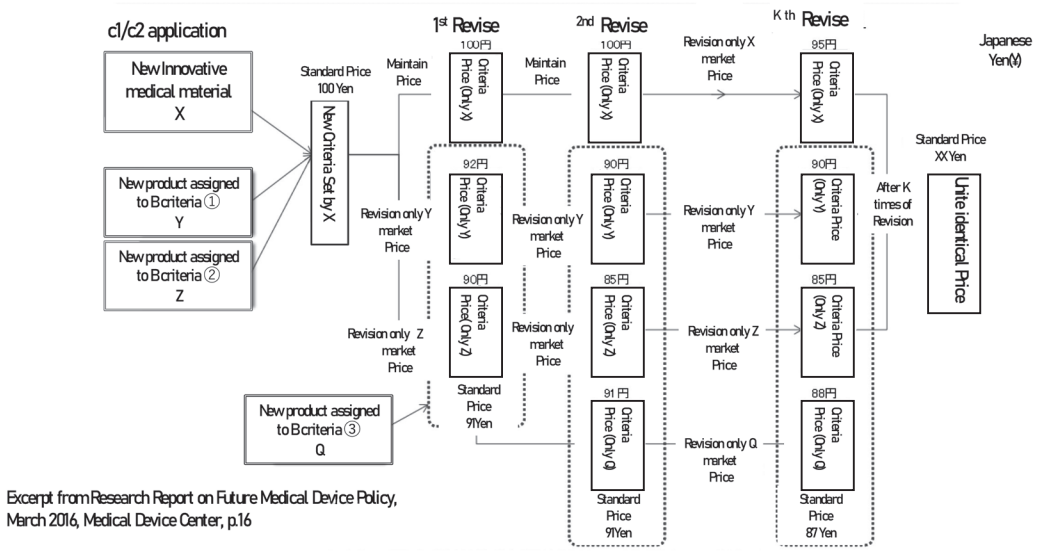
Nevertheless, if we are to expect growth in the medical device industry as a leading Japanese industry in the future, we need to reward innovative products through appropriate evaluation and enhance motivation more strongly throughout the industry. What specific measures might therefore be available to achieve this? Here, we would like to introduce the draft report of the "Study Group

6 According to the Pharmaceuticals and Medical Devices Law, there are more than 4,000 generic names and more than 300,000 items. On the other hand, the number of drug items listed in the National Health Insurance drug price list (December 2019) is 16,805.

on Future Policy on Medical Devices," in which the author participated in as a member.

Currently, the "Special Measures for the Classification of Medical Function," a system that has already been introduced, has virtually the aspect of evaluating each brand. Based on this system, the scope and operation of the system are defined as the "Medical Device Version Brand Evaluation System" by establishing rules and expanding the price maintenance period for a certain period.

Figure 3: Proposal on New Innovative Medical Material Price Revision Scheme



Under this system, based on the assumption that the new and innovative medical material X creates a new functional category, the following criteria shall be uniform: (1) the estimated future redemption price for each product within the functional category shall be determined based on the actual market price for each product; (2) the base price of the product other than product X shall be determined in advance based on the price of the product other than product X; (3) the maintenance of the initial price for product X shall be permitted for a certain number of revisions or for a certain period of time; (4) the base price of the material shall be uniform for a certain number of times or after the expiration of a certain period of time.

Needless to say, the scope of application of this system needs to be regulated in advance by constraints such as the size of the market, in consideration of the amount of administrative burden. What should be considered at the same time as the introduction of the "Medical Device Version Brand Evaluation System" mentioned above is the treatment of specified insurance medical materials that are not covered by this system. In view of the fact that the relative amount of money made available under this rule is low, what should be done in the direction of dealing with this issue in a comprehensive range of technical areas. By creating a comprehensive technology fee system, the conventional functional classification system will be streamlined, and as a whole, it is expected to have some effect on the rationalization of medical expenses related to medical devices. On the other hand, it should be emphasized that the inclusion of a product within a technology fee package is not only a disadvantage for a company. In the discussion of reimbursement revisions, the reduction of technical fees has more "downward rigidity" than the price reductions for individual medical devices. The ability to maintain product prices in a comprehensive package depends on negotiations

with medical institutions through wholesalers.

The provision of incentives to promote the sustainable introduction of innovative products and the rationalization of healthcare costs are both serious social requirements. As a realistic improvement measure based on the current system, it is necessary to simultaneously consider the establishment of the "Medical Device Version Brand Evaluation" system, which applies the special system for functional classification introduced in recent years, and the further promotion of comprehensive evaluation of technical fees.

3.3 Promoting International Expansion

The Basic Plan based on the Law for the Promotion of Medical Devices calls for the promotion of medical device exports and international cooperation and deployment. The former is mainly expected to contribute to Japan's economy, and the latter is considered to be intended to play a role in Japan's international contribution in a broader sense. With regard to the promotion of medical device exports, it is natural to rectify the economic imbalance in which the trade balance of medical devices has come to have a large excess of imports. Moreover, it is difficult to forecast significant growth over the medium to long term in the Japanese market as a whole due to rapid population decline in the future, and it is essential to develop overseas markets, especially in the so-called domestically-owned medical device companies that have depended heavily on the domestic market. Considering the growth factors of Japan's national income, such as GDP, expanding external demand, which is expected to grow significantly, is a major pillar that supports Japan's sustainable development.

In emerging and developing countries, medical needs differ from those in Japan and other developed countries. At the same time, it is presumed that the medical care provision system is deficient in terms of facilities and human resources. In addition, it is necessary to establish a system to provide healthcare that is indigenous to each region based on the customs and culture unique to each region. Against this backdrop, it is necessary to optimize the introduction of technology not only in the technical context of bringing in existing technologies, but also in the social context of what needs exist and how much infrastructure exists. It is hoped that the provision and dissemination of knowledge and know-how on Japan's medical system itself, which is highly appreciated by other countries, will promote the improvement and development of the welfare of the people of the recipient country, and that the export of medical devices and medical technology will expand in line with the development process. Harmonization of international regulations and standardization of various medical devices through international standards will prevent the "Galápagos syndrome" of elemental technologies and facilitate technology transfer between countries, thereby helping to promote smooth technology diffusion. The adoption of international standards and specifications in accordance with Japan's medical devices and technology will reduce the export hurdles for medical devices from Japan, including the reduction of costs associated with changes in specifications by export destination. It is necessary for the government, relevant organizations[7], and the private sector to work together in a strategic manner with a view to expanding national interests over the medium to long term.

---

7 The "Medical Globalization Task Force" has been set up under the Health and Medical Strategy Promotion Headquarters headed by the Prime Minister, and the General Incorporated Association Medical Excellence Japan (MEJ), the Japan International Cooperation Agency (JICA), the Japan Bank for International Cooperation (JBIC), the Japan External Trade Organization (JETRO), the Pharmaceuticals and Medical Devices Agency (PMDA) and other relevant organizations, as well as related ministries and agencies share information and implement the PDCA cycle.

3.4 Securing a Stable Supply System

With respect to medical devices, it is set forth that "the marketing authorization holder shall, unless there is an unavoidable justifiable reason, sell the device without delay after the application of the insurance, commence the supply of the device to the medical institution, and provide the device in a stable manner." If the supply of medical equipment, which is essential for medical practice, is interrupted, it will be difficult to continue medical care. Therefore, the stable supply of medical equipment is one of the most important issues for ensuring the safety of people's lives. Under the Declaration of Emergency Situation accompanying the spread of the new coronavirus infection, the stable supply of drugs and medical devices was hampered, and problems related to these supply systems, which had not been sufficiently recognized thus far, became apparent. A certain number of issues have already been sorted out through public-private dialogue, and concrete actions have been taken to revise the supply system. In order to secure a stable supply system for necessary medical devices, an integrated response is required from the following points. The first is the selection of equipment that requires special consideration for ensuring stability due to the necessity and importance of medical treatment. The second is to estimate demand in an emergency and to secure stockpiles and inventories that exceed the normal supply capacity. The third objective is to diversify supply chains, including the securing of means of transportation. Fourth is the establishment of a multi-tiered support system in the event that a stable supply is likely to be impaired and a proactive response in the event that it is impaired.

First, in light of the current case, these include consumables related to artificial respiration, pulse oximetry, cannula for ECMO, various testing instruments, and sampling instruments. In the future, it will be necessary to select a wide range of necessary equipment not only in the event of a pandemic but also in the event of a large-scale accident or disaster.

Second, in order to meet emergency demand, stockpiling is required from normal times, but it is also necessary to take into account the differences in the risk of occurrence in each region and the flexibility of the supply network. It is also important to keep track of the normal supply volume of manufacturers and the maximum supply volume in an emergency at the same time, and to disperse stockpiling and share the stockpiling status in each region.

Third, excessive dependence on foreign companies may result in an unnecessary supply of goods and services produced in Japan and the stable domestic supply may be impaired due to such factors as lock-in by the producing countries in the event of a global pandemic. In the midst of the globalization of the economy, the production of medical equipment has been optimized across borders in terms of materials and labor costs. In terms of equipment components, there are many cases in which production sites are located in multiple countries. Although the fundamental solution to this problem is the domestic production of necessary medical devices, it is often difficult to make a management decision that takes into account the cost and technical aspects. In reality, it is necessary to secure a domestic base for the production of medical devices, while at the same time taking both domestic and international measures to secure a multilayered and pluralistic supply network overseas in order to avoid excessive dependence on specific countries[8].

Fourth, in order to avoid, as far as possible, confusion in the medical field, it is essential to inform the public in advance and clarify the response policy in the event that there is a risk of supply

8 In order to encourage companies that actually have overseas production bases to secure production bases in Japan, as a supplementary budget for fiscal 2020, the "subsidies for domestic investment promotion projects for supply chain measures" (220 billion yen), and the "overseas supply chain diversification support project" (23.5 billion yen) has been allocated for the purpose of supporting the introduction of equipment for the purpose of diversification of ASEAN supply chains.

anxiety. Especially when the market share of medical devices is heavily dependent on a specific company, the impact is significant. Therefore, it is necessary to strictly observe the rule to "report to the Ministry of Health, Labor and Welfare (MHLW) without delay" if there is a risk of disruption of a stable supply. In the future, it is also possible to establish opportunities for enterprises that have a certain level of superiority in market share among the first-mentioned "equipment that requires special consideration for ensuring stability due to medical needs and importance" to share information on the supply system on a regular basis and to confirm the policy for ensuring a stable supply as appropriate. In the event of an unexpected emergency, such as the pandemic or supply uncertainty, it is possible that the industry will obtain prior approval and mutual approval of products with alternative functions as soon as possible[9].

From the viewpoint of "economic security," the government is working to establish a new fiscal support system to build a supply chain in order to maintain the domestic supply of goods essential for social and economic activities in times of emergency. In particular, the stable supply of essential goods in the medical field should be considered a matter of utmost priority. However, if the scope of application is incorrectly covered, the withdrawal of inefficient enterprises under the cover of "stable supply" will not proceed, and the competitiveness of the entire industry will weaken. While there are "unprofitable" factors that hinder stable supply, the perspective of simultaneously examining the causes of the "unprofitable" is also required.

3.5 Improvement of industry's own communication capacity and enhancement of industrial and policy research

The medical device industry plays an important role in Japan from each of the following perspectives: substantial contribution to medical care by the industry; impact on insurance finances; and role of leading the future economy of Japan as a knowledge-intensive industry. However, the diversity, breadth, and large majority of the content of the industry have made it difficult to see the overall picture of the industry from outside. In addition, even if there is a certain degree of coherence within the industry in the fields of diagnostic, therapeutic, and domestic/foreign investment, the accumulation and analysis of statistical data that can assist a systematic and uniform grasp of the overall situation, as well as the recommendations from the industry based on these data, are recognized as activities that require energetic implementation by the Japan Federation of Medical Devices, but efforts are still insufficient in comparison with their importance.

Against a backdrop of similar circumstances, we have seen no previous examples of articles that comprehensively and uniformly analyze the medical device industry. This was also considered to be a factor that made it difficult to expand the number of researchers interested in the industry and wanting to include it in the scope of their own research and analysis. The basic plan based on the Medical Devices Promotion Law calls for the development of leaders who will create innovation. However, the current status of researchers and specialists who think about policies that should be taken into consideration in the medical device industry has hardly developed at all.

It is my sincere hope that this article will stimulate public interest and understanding in the medical device industry not only among the people concerned in the medical device industry and among government officials, but also among a broad range of people, and that it will lead to the development of the industry in the future and the deepening of discussions for the improvement of

9 For example, in the event of an unforeseen transportation disruption, railway companies promptly implement "alternative transportation." According to the implementation report of the operational audit of JR East, "Regarding alternative transportation, JR East has established an alternative transportation pattern for each line section through mutual direct operation or consultation with other companies' lines that connect to each other to ensure smooth implementation. This is an ongoing effort."

the welfare of patients and the general public.

REFERENCES

Japan Association for the Advancement of Medical Equipment (JAAME) (2016) “Research Report on Future Policy for Medical Devices”, https://www.jaame.or.jp/mdsi/pdf/activity/final-report201603.pdf

Satoshi Sano (2012) “Impact of the System of Extension of the Term of Patent Rights on R&D Investment in New Drugs” Japanese Journal of the Japanese Society of Intellectual Property Vol. 9 No. 2 - 2012: 69 - 88.

Takayuki Ishikawa (2023) “Data Construction and Productivity Analysis on the Medical Device Manufacturing Industry in Japan” Journal of International Economic Studies, No.37. p5-21.

Cabinet decision (2016) “Basic Plan for Promotion of Research, Development and Dissemination of Medical Devices for Improvement of the Quality of Medical Devices Received by the Public”, https://www.mhlw.go.jp/files/04-Houdouhapyou-10807000-Iseikyoku-Keizaika/0000125967.pdf

Instructions for Contributor

1. The text should be in single-column format and typed in English using double spacing and wide margins on paper of approximately 21cm by 29.6cm. Each manuscript should be organized in the following order: title page, abstract of 100 ～ 150 words, JEL classification number(s), text (with notes, references, and captions for figures and tables), acknowledgement, The title page consists of the title of the paper, the full name(s) and the institutional affiliation of the author(s).

2. Please make sure not to embed "graphically designed" figures or tables, but prepare these using the PC software's facility. Don't import tables or figures into the text file but, instead indicate their approximate locations directly in the text. Only monochrome figure can be accepted. Color figures or illustrations must be converted to their monochrome counterparts.

3. Original articles only will be considered. Copyright to the article is transferred to the Institute of Comparative Economic Studies, Hosei University, effective if and when the article is accepted for publication in the *Journal of International Economic Studies*. The length of an original article should not exceed 8000 words and thirty pages in draft, including an abstract, tables, figures, acknowledgements, notes and references.

4. Notes should be numbered as a following example:
   At this date, the level of urbanization[2] can be estimated at 12.3 per cent.

5. References should be cited in the text by giving the surname of the author(s) with the year of publication as following examples:
   This is due to the fact that the process of economic development and modernization began first in the less urbanized countries (Bairoch, 1985, Chap. 16);
   Muth (1969) shows that the income elasticity of demand for housing is greater than unity;
   Thus, 'the apparent trend to a large non-proletarian "middle-class" has resolved itself into the creation of a large proletariat in a new form' (Braverman, 1974, p. 355).
   The full list of references should be given alphabetically by the first author's family name, at the end of the manuscript. They should be written using the following examples.
   Akabane, Y. (1970), Keizai Togo to Kokumin Keizai (Economic Integration and National Economy), in Miyazaki, Y.*et al. Gendai Shihon Shugi-ron* (*Modern Capitalism*), Chikuma Shobo, Tokyo, pp. 173-232.
   Esho, H. (1981), Tojo-koku Hi-seido-teki Noson Shin'yo Shijoron (Towards the Analysis on the Non-Institutional Rural Credit Markets in Developing Countries), *Keizai Shirin* (The Hosei *University Economic Review*), Vol. XLIII, No. 4, pp.113-65.
   Gannicott, K. (1986), Women, Wages, and Discrimination : Some Evidence from Taiwan, *Economic Development and Cultural Change*, Vol. 34, pp.721-30.
   Gerschenkron, A.(1962), *Economic Backwardness in Historical Perspective: A Book of Essays,* Harvard University Press, Cambridge.
   Minami, R. (1981), *Nihon no Keizai Hatten* (*Economic Development of Japan*), Tokyo Keizai Shimpo-Sha, Tokyo.
   Weiskopf, T.E. (1971), Alternative Patterns of Import Substitution in India, in Chenery, H. B. (ed) *Studies in Development Planning*, Harvard University Press, Cambridge and London, pp.95-121.

6. Authors will receive the first proofs for correction. Major revisions of the text at that time will not be possible. Fifty copies of each printing will be provided to the author at the expense of the Institute.

7. Manuscripts should be e-mailed both in source files (which means in any of the document file and/or spreadsheet file) and PDF format to jies@ml.hosei.ac.jp, Editorial Board for JIES.
   The Institute of Comparative Economic Studies
   Hosei University
   4342 Aihara-machi, Machida-shi
   Tokyo 194-0298, Japan

8. Inquiries may be made to the Institute at the following e-mail address:
   e-mail: jies@ml.hosei.ac.jp

ICES