

AMDD *Vol.18*

NEWSLETTER

January 2015

English translation of Japanese newsletter

CONTENTS

- Current Situation and Issues in Occupational Safety and Health for Handling Anti-Cancer Drugs in Japan
- Voice from the Local Government: Hiroshima's Medical and Welfare Device Industry Paving the Way to the Future: Aim for New Advances in the Prefecture of Manufacturing
- Patient's Voice: Receiving the Treatment that's Right for Me
- Enforcing the Pharmaceuticals and Medical Devices Act
- New Year's Greetings: A Year of Accelerated Innovation
- 6th Annual New Year's Party Held
- AMDD Sponsored and Exhibited at Medical Creation Fukushima 2014
- Future Medical Trends Resulting from the 2014 Reimbursement Revision

Current Situation and Issues in Occupational Safety and Health for Handling Anti-Cancer Drugs in Japan

The National Institute of Occupational Safety and Health (NIOSH) was quick to tackle the problem of the effects on the health and safety of health care workers when exposed to anti-cancer drugs — an issue which there was previously little opportunity to address. Dr. Shigeki Koda, the Institute's chief researcher, spoke on the present situation and the issues involved.

A Look at Japan's Current Situation

Medical settings are workplaces where medical workers are constantly exposed to physical energy (e.g. radiation), chemicals, bacteria, viruses, and other harmful agents that can damage their health. Occupational safety and health research for health care workers have long been carried out in the West; NIOSH (the National Institute of Occupational Safety and Health) in the US published guidelines in 1988. NIOSH proposed measures for preventing exposure to anti-cancer drugs and other hazardous drugs in 2004, due to the risks when handled including skin damage, sterility, miscarriages, leukemia, and cancer.

On the other hand, in Japan, there has not been much interest in occupational safety until now. I remember being shocked when doctors attending my lectures say that they have never been told about the harm caused by anti-cancer drugs. There are few opportunities to learn about these risks during medical training in Japan, and until recently, even health care workers were misinformed on the subject.

In order to rectify this situation, we at JNIOOSH have been conducting a research project related to safety during the handling of anti-cancer drugs. Urine tests on health care workers who handle anti-cancer drugs have detected the presence of anti-cancer drugs — albeit in minute amounts — thus confirming that exposure occurs even in Japan.

As recently as 2004, nurses at some hospital prepared medication at nursing stations wearing only regular lab coats, no masks, and no protection other than thin gloves. Then a program was implemented which introduced biological safety cabinets (BSC), and required caps, masks, gowns, and thick gloves to be worn. This made it possible to prepare medications under sterile conditions and reduced exposure. Introducing the equipment proved effective, but in order to reduce the risk even further, it was necessary to utilize closed systems (closed connected equipment) and adopt BSCs with exhaust equipment that vented outside.

Future Issues

Administrative guidance on “measures to prevent exposure to anti-cancer drugs” was issued in Japan in May 2014. It recommends adopting and using BSCs and closed systems. The results of the survey we requested from hospitals that serve as cancer centers showed that facilities and equipment were satisfactory, but the practices of personnel were still inadequate. I think it is important to find a way to increase the understanding of the risks and hazards for handling anti-cancer drugs in medical settings for health care workers. Other issues that need to be addressed include clarifying whether or not uniform measures can be applied on the basis of hospital size, and the need for self-regulating the handling of anti-cancer drugs.

* The lecture provided by Dr. Koda was summarized by the editorial desk.



Dr. Shigeki Koda
Chief Researcher
Research Proposal Coordination Department
The National Institute of Occupational Safety and Health

Dr. Koda graduated from the Faculty of Medicine at Akita University in 1984. He finished his postgraduate studies at the Okayama University Graduate School of Medicine in 1988. His posts include lecturer at Okayama University’s Faculty of Medicine in 1990, visiting researcher at the Rollins School of Public Health at Emory University in 1992, professor at Kochi Medical School in 2001, and professor at Kochi University’s Medical Faculty in 2003. He has held his current post since 2006.

Voice from the Local Government

Hiroshima's Health and Welfare Device Industry Paving the Way to the Future

Aim for New Advances in the Prefecture of Manufacturing



Hidehiko Yuzaki
Governor of Hiroshima Prefecture

Hiroshima Prefecture has the highest concentration of industry in the Chugoku-Shikoku region, including numerous one-of-a-kind companies possessing world-leading technology and top companies with large market shares in their respective fields. The prefecture is taking advantage of its world-class manufacturing technology and has established its “Hiroshima Vision for New Industry Growth” (instituted July 2011). This initiative is devoted to cultivating healthcare and welfare-related fields to create new industries that can maximize the prefecture’s potential, which is expected to create growth in the future. The prefecture established an action plan for attracting healthcare-related companies in July 2012. The plan provides safe and reliable health and welfare services on a day-to-day basis by creating business models and developing high-quality equipment that takes advantage of Hiroshima technology.

In the roughly three years since the start of this program, we have offered support for businesses actively engaged in developing new products in the medical device industry, expanding their operations, or entering the market from other fields. For example, we inaugurated the Workshop for Medical-related Industries of Hiroshima in November 2011, and have conducted drug seminars, market entry seminars, and medical industry news release conferences approximately once per month. We have also appointed five special coordinators at the Hiroshima Industrial Promotion Organization; each provides comprehensive support in his or her field of expertise in areas ranging from corporate product development to drug certification and sales expansion. Hiroshima has also established a subsidy system (the Hiroshima Medical-Related Business Creation Financial Support Fund) and R&D services (a device development pilot project for solving medical and welfare-related issues) to assist with credit needs. The prefecture also provides wide-ranging support by supplying the finances needed for R&D and sales expansion to help companies bring new products and services to market. The result has been gradual growth, including over 20 projects that have turned into products as well as new manufacturing or manufacturing/sales permits for medical devices obtained by ten companies.

Going forward, Hiroshima will promote new initiatives under “Hiroshima Hatsu” (Hiroshima-developed). One area to watch is the Hiroshima Healthcare Demonstration Field, which will be developed starting from next year. The demonstration field is an initiative to actively involve medical institutions, welfare facilities, universities, and other such organizations within Hiroshima Prefecture in processes that involve difficult hurdles for individual corporations. These hurdles include clinical trials, experiments, and assessments, which are needed for bringing products to market and expanding sales, in

order to develop and improve products and services. We have set up a system for securing ideal demonstration partners in accordance with the respective challenges, providing rapid support for procedures of all kinds, and making arrangements with related institutions to begin full-fledged operations for the following year. Of course, we are seeking ideas from around the country, not just from companies within the prefecture. We would like any interested companies to consider choosing Hiroshima Prefecture as a partner.

Additionally, in order to provide better healthcare for everyone in the region, we are currently building the Hiroshima High-Precision Radiation Therapy Center (provisional name) in a location five-minute walk from Hiroshima Station. This facility is distinctive in that it will be based on bed-less outpatient treatment, provide medical care that does not alter patient lifestyles, and treatment will be provided through cooperation with the city of Hiroshima's four core hospitals (Hiroshima University Hospital, Hiroshima Prefectural Hospital, Hiroshima City Hiroshima Citizens Hospital, and Hiroshima Red Cross Hospital & Atomic Bomb Survivors Hospital). Equipped with the latest high-precision linear accelerator, it will begin operations in fall of 2015.

Furthermore, we are actively considering global development and regional partnerships. We have conducted information exchanges to learn about the latest development techniques in the US and engaged in mutual endeavors: in January 2013, a delegation led by AMDD director John Harris was invited to a research seminar and we attended a talk on partnering with Japanese manufacturing companies; additionally, I attended the US-Japan Council's Governors' Meeting and paid visits to Stanford University Biodesign Program's Clark Center and the Fogarty Institute for Innovation.

Going forward, Hiroshima Prefecture intends to build stronger relationships with AMDD members and other leaders in the global healthcare industry, and to cooperate on more joint development initiatives.

We humbly ask for your continued support.



Left: The US-Japan Council Governors' Meeting
Right: Hiroshima High-Precision Radiation Therapy Center (rendering of proposed facilities)

Patient's Voice

Receiving the Treatment that's Right for Me



Kyoko Nakata, Director
MS Cabin (an authorized nonprofit organization)

Multiple sclerosis (MS) is an intractable neurological disease that occurs when the immune system mistakenly attacks the brain, spinal cord, and optic nerve. The cause is unknown and there are no drugs that can cure it. As of 2013, some 23 million people worldwide are estimated to have the disease, which is common in the West. In Japan, 17,073 people were recognized as having MS in 2012, and that number grows each year. The onset of MS usually occurs in young people between their twenties and forties. The disease has a serious impact on people's social lives, and most have difficulty working. Several preventative drugs that impede the disease's progress have been developed, and thanks to these drugs, the number of people able to lead normal lives has grown. However, there are currently problems with how those drugs are used, because MS varies greatly from person to person, and MS treatments also vary in responsiveness. Some patients diagnosed with MS do not benefit from these drugs, and in unfortunate cases, they can even make the disease worse. One condition that can have this effect is neuromyelitis optica (NMO).

NMO is a disease caused by auto-antibodies in the blood, and it has been diagnosed as MS up until now. Since NMO auto-antibodies were discovered some years ago, the two diseases are now distinguished from each other as it is understood that treatments for MS can cause NMO to worsen. Today, NMO is treated separately from MS.

That said, there is also a gray zone consisting of "MS-like NMO" and "NMO-like MS" — conditions that do not fit cleanly into either category. Specialists continue to perform research that assumes multiple pathologies under the category of MS. But since there are no clear standards for diagnosis or treatment within this gray zone at the present stage, the patient's prognosis depends on the skills of the doctor in charge.

I am incredibly grateful for the progress that has been made in developing these drug treatments, but if it weren't for accurate diagnosis in the first place, patients wouldn't know what treatment was right for them. My hope is for people to be enabled to understand their own medical condition and what treatment is best for them.

One of MS Cabin's activities for sharing information on MS and NMO is the medical treatment forum we host at the end of each year. Patients and their families can learn about the latest information along with companies and medical workers. 511 people participated in 2014, of whom 78 were corporate participants. Nearly all corporate participants were from drug companies, and unfortunately participants from diagnosis drug-related companies did not reach double digits. We are acutely aware this was due to our own shortcomings.

I would request your continued cooperation so that MS and NMO patients can receive the treatment that's right for them, and we will do everything we can to make that happen.

MS Cabin • <http://www.ms-cabin.org>

The Pharmaceuticals and Medical Devices Act

The Pharmaceuticals and Medical Devices Act (as it is called in its shortened form) has finally been enforced. Under this act, medical devices, which were included under “pharmaceuticals, etc.” in the previous law, are now treated independently both in name and reality.

The problem of drug-induced hepatitis was given as one of the triggers that prompted stronger safety measures in this revision of the law, but separating the chapter on medical devices based on their characteristics is also significant for us. I would like to provide a summary of the main changes from the Pharmaceutical Affairs Law.

1. QMS and the shift to a registration system for manufacturers

Approval/authorization for medical device manufacturers is carried out by registering under the new act. However, it is not accurate to regard this as just a simple deregulation.

Manufacturers now undergo a registration procedure that accommodates the rapid improvement cycle of medical devices based on manufacturing and quality control systems as a “whole”, and not the individual management of each manufacturing process. From now on, marketing authorization holders (MAHs) will have the rights and responsibilities over the entire quality management system (QMS), including manufacturers.

Even in cases involving overseas manufacturers (the parent company) and Japanese MAHs (the subsidiary), the MAH subsidiary is legally responsible for the entire QMS, including the parent manufacturer. However, in reality, the subsidiary has to follow the direction of the parent company.

We want to streamline the quality management systems by creating a division of roles consistent with both legal compliance and the reality, and by organizing registered manufacturing plants and product lines.

2. Regulating standalone programs as medical devices

Standalone programs are treated as medical devices under this act. This puts Japan on par with the West, where the programs were already treated as medical devices.

Handling applications for standalone programs and criteria for judging medical device as standalone health and medical-related programs that can be installed on smartphones and tablets are matters currently being examined.

There is the potential for the development of unforeseeable programs in the IT field, so we hope that government agencies and industrial associations will formulate flexible operational rules to allow suitable development in this field.

3. The evaluation systems on performance of usage

The Post-Marketing Surveillance System has been renamed the “Evaluation System on Performance of Usage”, under which each case as well as its duration are now determined individually.

From now, even though a new medical device might not be subject to the Evaluation System, an improved medical device might become subject to the Evaluation System. It is reasonable for the system not to be applied uniformly. However, predicting whether the Evaluation System is applicable or not will require operational decision-making criteria that satisfies both applicants and reviewers, and guarantees transparency in that process.

Going forward, in-depth discussions between the government and industry associations will be needed in order to disseminate this information.

The transition between this act’s promulgation and its enforcement has only been one year, and examining its level of practicality needs to continue. Several matters carried over from before the act’s revision continues to be examined, including the scope within which applications for partial changes are required.

During examinations, both applicants and reviewers, especially the PMDA and the third-party certification agents, need to aim for reasonable operations based on the concepts laid out in the new act. The new act will only be effective once true “collaboration” takes place. This means applicants develop products and submit applications based on a constructive interpretation of the act’s requirements, and reviewers apply new judgments based on the characteristics of the medical devices in question and not on past judgments.



Masanori Otake
Regulatory Affairs and Policy (Healthcare) Manager
GE Japan



New Year's Greetings: A Year of Accelerated Innovation

Here at the start of 2015, I would like to deliver a brief message on behalf of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD).

With the Act for Ensuring Quality, Effectiveness and Safety of Pharmaceutical Products and Medical Devices (the Pharmaceuticals and Medical Devices Act for short) being enacted in November last year after being established a year earlier, and the Japanese Agency for Medical Research and Development (AMED) being established in April this year, expectations are high for an increase in healthcare innovations under the Abe administration. However, even though the Pharmaceuticals and Medical Devices Act is now in effect, numerous issues regarding the details have arisen. The need for these issues to be resolved individually through collaboration with the government will need to continue as we aim for smoother operations and the creation of a better business environment.

For starters, 2015 holds great promise with respect to the biannual reimbursement revision that will take place in April 2016. In addition to requesting evaluations of valid innovations resulting from new advanced medical technologies developed up until now, the cost of special treatment materials based on foreign average prices during reimbursement revisions continues to decline. We continue to insist that foreign average prices and the problem of the difference between domestic and foreign prices, which are of concern to us, have already ended this historic mission.

Additionally, with regard to eliminating device lag and the device gap that has significantly progressed in recent years, we initiated a new medium-term (three-year) plan last year at the Pharmaceuticals and Medical Devices Agency (PMDA), and we have been participating in a five-year collaborative plan with PMDA. The plans call upon all AMDD member companies to strive to eliminate lag before submitting applications, and to speed up the approval process.

This year, it is our intention for AMDD to cooperate with AdvaMed, the US government, the US embassy, and other medical device-related organizations, and convey through our activities the attitudes and demands of manufacturers to the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and other related agencies. We at AMDD will strive to achieve even quicker implementation of advanced medical devices in the future, and I would greatly value your guidance and assistance in our efforts this year.

Takashi Shimada
President, Medtronic Japan Co., Ltd.
Chairman, American Medical Devices and Diagnostics Manufacturers' Association
(AMDD)

6th Annual New Year's Party Held

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held its 6th Annual New Year's Party on January 13, 2015. In his New Year's greetings, Chairman Takashi Shimada (President of Medtronic Japan Co., Ltd.) expressed his enthusiasm toward cooperating further with related organizations on resolving the details of the Pharmaceuticals and Medical Devices Act enforced last year.

Describing his ambitions, he said, "The existing value of medical devices and diagnostic drugs can now be properly recognized, and this is a field with potential for growth when it comes to the Japanese economy. I want AMDD to contribute to this growth as much as possible."

In messages by guest speakers, Yuji Kanda, head of the Pharmaceutical and Food Safety Bureau at the Ministry of Health, Labour and Welfare, expressed his desire to have a substantial exchange of views involving everyone in the industry regarding the full-fledged enforcement of the Pharmaceuticals and Medical Devices Act. Andrew Wylegala, the Senior Commercial Officer at the US Embassy, reflected on how important 2014 had been for US-Japan relations due to visits by President Obama and Secretary of Commerce Penny Pritzker. Koji Nakao, Chairman of the Japan Federation of Medical Devices Association, emphasized the need for a comprehensive perspective not restricted to the framework of medical devices and the need for rapid engagement in anticipation of the year 2025 problem, based on the question, "what can be done to improve public healthcare?"

Afterwards, Kenichi Matsumoto, Director of the Japan Association of Medical Devices Industries, provided a toast and members celebrated the New Year with guests from various sectors, including the Ministry of Health, Labour and Welfare and the PMDA.



Left: AMDD Chairman Takashi Shimada
Right: 6th Annual New Year's Celebration

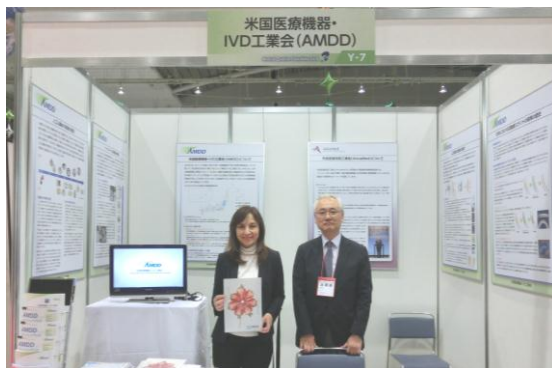
AMDD Sponsored and Exhibited at Medical Creation Fukushima 2014

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) sponsored and exhibited a booth at Medical Creation Fukushima 2014, an event held in Koriyama, Fukushima on October 29 and 30, 2014.

This was the tenth time the event was held. Compared to previous years, more comprehensive technology exchanges and business discussions took place through exhibits for both products by major medical device manufacturers and technologies by manufacturers in other fields. The aim is to develop Fukushima into a “world-class medical device and equipment manufacturing center”.

This was AMDD's third time participating. Visitors from a variety of industries visited the AMDD booth, including those who have been instrumental in collaborating with local governments beginning in 2013, and many interesting topics were raised.

Additionally, this year's event attracted companies and organizations promoting industry-government-academia partnerships not only from the Tohoku region, but also from Hiroshima, Miyazaki, and Oita.



Left: The AMDD booth
Right: The Past 10 Years

Future Healthcare Trends in Light of the 2014 Medical Payment Revisions

By the time this newsletter is released, elections for the Japanese House of Representatives will have ended, and the government will likely have begun work on a new framework for medical payments. From a healthcare perspective, things don't look too promising. The reason is that the increased consumption tax rate to 10% has been postponed for 18 months, and the funding that would have been allocated to pensions and healthcare has dried up. Looking back, I think things were better under the Democratic Party of Japan's administration, as far as healthcare is concerned, and I'm probably not alone.

It would not be an exaggeration to say that the recent revisions included an unprecedented number of negative revisions. Revisions to the portion of consumption tax obtained from declining drug costs was an extreme violation of the rules.

Additionally, due to the creation of local comprehensive care hospitals, patients in the hyperacute phase of hospitalization to long-term bed care are being asked to recover at home. This marks the start of an entirely new healthcare system. However, if we look at the revisions of 2010 and 2012, there are numerous warning signs in the seemingly unexpected revisions of those years. In other words, the trends we see in these reimbursement revisions certainly indicate the looming year 2025 problem. With that in mind, I would like to discuss the 2014 reimbursement revisions as well as future trends in healthcare in light of these revisions.

1. All healthcare institutions pushed for at-home recovery

The latest revisions push for at-home recovery for all patients ranging from the hyperacute phase of hospitalization to the chronic-phase bed care. One reason is that in 2025 when the baby boom generation reaches old age, the current number of hospital beds will be completely inadequate. The goal is to make effective use of hospital beds. That way, hospitals will not be the final location for chronic bed care patients; the goal is to have them return home if medical treatment is unnecessary. The Ministry of Health, Labour and Welfare calls this “providing healthcare that does not cause lifestyle fragmentation”.

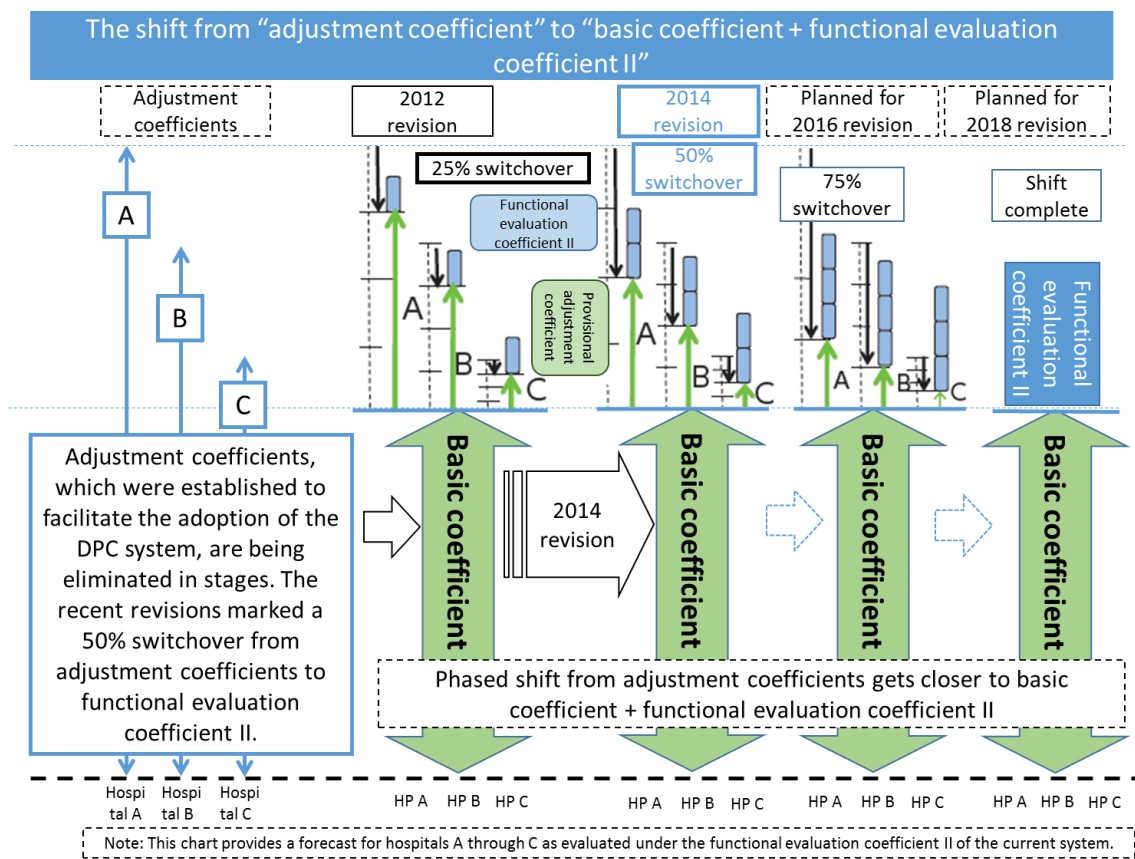
2. Promoting functional differentiation of healthcare

The Japanese health insurance system is an incredibly wonderful healthcare system, but now that 50 years have passed since its establishment, a variety of problems have been exposed. One opinion is that outpatients are concentrated at major hospitals, and the hospitals that ought to be focusing on actual hospitalization and treatment are exhausted. Thus, hospitals with 500 or more beds give priority to patients with letters of recommendation; hospitals with a low introduction rate or reverse introduction rate incur penalties. This is a sound direction and approach to take, but when the profitability of today's hospitals is considered, outpatients account for roughly 30% of earnings, with a hospital's outpatients becoming a source for inpatients, so a better solution is needed.

Another problem is the 7:1 bed-to-nurse ratio. At present, the 7:1 is the ratio applies to over 3.5 million beds. This accounts for about 40% of all beds. It is very doubtful whether this many seriously ill patients exist. With the latest payment revisions, the Ministry of Finance indicated that medical expenses were not being efficiently utilized, and this was a major reason for the negative revisions. With this in mind, five items were reexamined, and a reduction of roughly 90,000 beds was expected, but unfortunately, that doesn't seem to have happened. We can expect stricter terms to be added in the future.

3. DPC revisions

Concurrent to the recent revisions, certain necessary measures were conducted based on the overall revision policy, including a revision of the diagnostic classification points table as well as the establishment of coefficients specific to individual medical institutions. Additionally, with regards to the adjustment coefficients established for facilitating the smooth adoption of this system, the past three revisions, which includes the latest revision, are being conducted with the goal of a phased switch to basic coefficients and functional evaluation coefficients II, and that phased switchover will continue (Fig. 1). One major issue during the latest revisions was managing the increase in the consumption tax rate. This was addressed by calculating the breakdown of hospitalization fees, drug costs, materials costs from the diagnosis procedure combination (DPC) data, and establishing the portion of consumption tax from each DPC. However, the difference after the drug cost revision with regards to revenue has resulted in lingering resentment toward future revisions.



Currently, the coefficients specific to medical institutions are comprised of the basic coefficient, functional evaluation coefficient I, functional evaluation coefficient II, and the provisional adjustment coefficient. Of these, the provisional adjustment coefficient will be eliminated in the 2018 revisions. It is being replaced with the basic coefficient and functional evaluation II coefficients. The switchover is 50% complete in the 2014 revision.

No major reexamination of the basic coefficient was conducted. That said, there was a reexamination of performance requirements related to the selection of DPC hospital group II. The changes assume requirements related to the implementation of doctor training at core clinical training hospitals, and that cooperative training has been removed from the

evaluation. Implementation of advanced medical technology is now based on a new draft plan according to the publication of *Gaihoren Shian* version 8.2.

The reexamination of functional evaluation coefficient II is shown in Table 2. This topic took up the most discussion time during the 2014 revisions. The essence of this coefficient is that it is positioned as an incentive for DPC-participating hospitals (an incentive for the roles and functions that a medical institution should provide). Of the previous six items, there is no change from the previous revision with regards to the efficiency index, complexity index, or coverage range index. The three remaining items were reexamined, and one item was added. The newly added evaluation was the “generic drug index”, and the weighting of the seven items has been evenly distributed. The generic drug index is set forth in the “roadmap for promoting greater usage of generic drugs”, created on the basis of the Outline of the Comprehensive Reform of the Social Security and Tax Systems (Feb. 17, 2012 cabinet decision), which establishes as a target value a share by quantity of 60% or greater for generic drugs. The generic drug usage proportion for DPC hospitals is 37.2%. The data shows a low fee-for-service portion at 30.1% and also recognizes the need to evaluate this portion for DPC.

Initially, the efficiency index was proposed as an item, but the predominant opinion at the DPC Subcommittee and Central Social Insurance Medical Council Fundamental Issues Subcommittee is that this would be inappropriate. As such, the efficiency index was added to the functional evaluation coefficient II under number 7. The incentives established here are higher than originally planned, with a maximum evaluation of 0.01544. Thus, medical institutions that have as of now, been inactive users of generic drugs, have simultaneously become more active. However, there is a strong possibility that this coefficient will be lowered next year.

4. Conclusion

Based on my overview and comments for the 2014 reimbursement revisions, the most important consideration is that our healthcare should be aboveboard, and that there should be transparency in all medical activities. Above all, while this system has both strengths and weaknesses, the next medical payment revisions will be based on our medical activities.

Medical activities are stored in a digital database as evidence; they will be used as resources for per-DPC evaluations and for setting medical institution-specific coefficients during the next medical payment revisions.

As a result, if we recklessly rush to slash costs, the discretionary powers for hospitals will also diminish. That has been the case with hospital re-admittance rules. However, the healthcare we provide is also proof that everything is noted by the Ministry of Health, Labour and Welfare. If we slice hairs and nitpick to ensure profitability, things will be tight and we will end up offering insufficient medical services. We must take to heart the fact that the healthcare we provide will be used as a resource for DPC reevaluations in two years. The ultimate goal of DPCs is to establish standardized, efficient, high-quality, safe medical treatment. I want you to have a good understanding of the rules and principles behind DPC/PDPS and provide medical services accordingly.

The submission of DPC data for the 2014 revisions was an obligation for all 7:1 hospitals and local comprehensive care hospitals, and incentives were provided to all hospitals to carry out opt-in data submission. As a result, healthcare becomes even more transparent and aboveboard. Regardless of the immediate medical payment revision evaluations, the most important thing is to continue providing high-quality healthcare in accordance with local needs; and that is what will result in profitable hospitals.

2014 Reimbursement Revisions

Reexamination of the DPC system (fixed payment calculation system for acute-phase hospitalization and treatment) (2)																	
Reexamination of functional evaluation coefficient II																	
<table border="1"> <thead> <tr> <th>Before revision</th> <th>After 2014 revision</th> </tr> </thead> <tbody> <tr> <td>1) Data submission index</td> <td>1) Health insurance treatment index (rev)</td> </tr> <tr> <td>2) Efficiency index</td> <td>2) Efficiency index</td> </tr> <tr> <td>3) Complexity index</td> <td>3) Complexity index</td> </tr> <tr> <td>4) Coverage rate index</td> <td>4) Coverage rate index</td> </tr> <tr> <td>5) Emergency treatment index</td> <td>5) Emergency treatment index</td> </tr> <tr> <td>6) Local treatment index</td> <td>6) Local treatment index</td> </tr> <tr> <td></td> <td>7) Generic drug index (new)</td> </tr> </tbody> </table>	Before revision	After 2014 revision	1) Data submission index	1) Health insurance treatment index (rev)	2) Efficiency index	2) Efficiency index	3) Complexity index	3) Complexity index	4) Coverage rate index	4) Coverage rate index	5) Emergency treatment index	5) Emergency treatment index	6) Local treatment index	6) Local treatment index		7) Generic drug index (new)	<p>1) Health insurance treatment index (revision of "data submission index") In addition to the "region unknown / specifics unknown code usage rate" that had been evaluated as the data submission index, new evaluation items have been added, including "entry contradictions between formats", "non-coded injury/illness name usage rate", and "dispatching medical training officials to educate on healthcare treatment (group I only)".</p> <p>5) Emergency treatment index Reexamine the evaluation qualifications of patients for whom serious illness hospitalization fees are being calculated, in order to be fairer in selecting patients who qualify for evaluations of this index.</p> <p>6) Local treatment index Reexamine the addition of evaluations related to "24-hour treatment systems for acute myocardial infarctions" and "admission systems for psychiatric physical complications".</p> <p>7) Generic drug index (new) Evaluate the usage of generic drugs on a quantity basis, based on the "roadmap for promoting greater usage of generic drugs" (new index).</p>
Before revision	After 2014 revision																
1) Data submission index	1) Health insurance treatment index (rev)																
2) Efficiency index	2) Efficiency index																
3) Complexity index	3) Complexity index																
4) Coverage rate index	4) Coverage rate index																
5) Emergency treatment index	5) Emergency treatment index																
6) Local treatment index	6) Local treatment index																
	7) Generic drug index (new)																
Reexamination of calculation rules																	
<p>1) Reexamination of "sequential" calculation rules during re-admittance to the same hospital (i.e. "three-day-or-less re-admittance rules") Conduct any reexamination necessary for extending the re-admittance period targeted by this rule from "3 days" to "7 days" based on case studies where patients are intentionally discharged within three days and then re-admitted on the fourth day or later, regardless of whether handling such cases sequentially would be appropriate according to the specifics of the treatment.</p> <p>2) Promoting adequate injury/illness name coding Conduct measures related to the drafting and publication of a "DPC injury/illness name coding text" in order to promote adequate injury name coding.</p>	<p>3) Handling drugs brought in during hospitalization In order to address cases in which patients bring drugs prescribed to them as outpatients prior to hospitalization, the use of drugs brought in to be used for injuries and sickness during hospitalization or planned hospitalization is to be generally prohibited while the patient is hospitalized.</p> <p>4) Reexamination of lump-sum payment grading methods for drugs on the first day of hospitalization Expanded application of grading method D, which underwent trial adoption under the 2012 revisions, to diagnosis procedure combinations (DPCs) involving cardiac catheter tests will be reexamined, and its usage will continue.</p>																



Nobuya Koyama
Professor emeritus at Toho University,
specially appointed professor in the Toho University Faculty of
Medicine

Dr. Koyama graduated from Toho University Faculty of Medicine in 1972. He became an instructor at the Toho University Faculty of Medicine in 1985. Numerous managerial posts held include: Department director of the Toho University Sakura Hospital Circulatory System Center in 1992; professor in the Toho University Thoracic and Cardiovascular Surgery Department in 1995; director of Toho University Omori Hospital in 2000; vice-director of Toho University Omori Hospital in 2010; present post, held since 2013. He served as Medical Payment Investigation Organization's DPC Evaluation Subcommittee chairman for MHLW's Central Social Insurance Medical Council. He served in public positions, including chairman of DPC working groups, director of the Japanese Association for Thoracic Surgery, and director of the Japanese Society for Cardiovascular Surgery.

Value of Medical Technology

Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

Note: All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.