



AMDD *vol.4*

NEWSLETTER

*English translation for internal use only

PAGE 1

CONTENTS

- New chairman's inaugural address
- The direction of medical care policy as seen in the medical fees revision
- Patient's Voice: Awaiting establishment of a treatment to completely cure liver cancer
- Medical Journalist Viewpoint: Preparation for the effective use of CT and MRI systems
- First New Year's party since the inauguration of AMDD
- Value of medical technology: Extending healthy life, starting with knees
- Advocacy committee formed in AMDD

New chairman's inaugural address

I, David W. Powell, was appointed second chairman of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) on April 1. Since 2008, I have served as president of Johnson & Johnson K.K., based in Tokyo, overseeing J&J's medical device businesses. I joined J&J in 2001, have nearly 20 years experience in the medical device industry, along with other professional experience.

Founded exactly one year ago, the AMDD represents the Japanese operations of 65 companies headquartered in the United States that provide medical devices, in-vitro diagnostics (IVD) and other advanced medical technology. AMDD members create jobs for about 13,000 people in Japan through various technologies ranging from artificial pacemakers, implantable cardioverter-defibrillators and prosthetic heart valves to catheters for percutaneous coronary intervention to stent grafts, artificial joints and other materials for plastic surgery to intraocular lenses to large-screen diagnostic devices to genetic diagnostics and IVD to system devices.

Our priority issue is to deliver the latest medical technology to Japanese patients as quickly as possible. I find it very unfortunate that many advanced medical technologies introduced in other countries worldwide with high appraisal are not possible to contribute for saving life and improving QOL of Japanese patients. To resolve such "device lags" and "device gaps," I hope to cooperate with AMDD members and hold discussions with relevant divisions of the Ministry of Health, Labour and Welfare regarding the problems faced by medical devices of all sizes and IVD.

Invigorating the Japanese medical technology industry requires that we cooperate with and make continuous proposals to groups in Japan and Europe, and seek appropriate pricing that promotes innovation in advanced medical technology. The AMDD will continue to



cooperate with the Japanese government, medical societies and related industry groups, maintain collaboration with the United States government and the Advanced Medical Technology Association (AdvaMed) based in the US, and promote activities that aim to realize the quick and appropriate introduction of advanced medical technology of a global standard to Japanese fields of health care and the overall control and appropriate distribution of medical expenses.

We will also strive to build close relationships with patients, medical professionals and policy makers, and together with our member companies, work toward valuable advances in medical technology in Japan. I look forward to your continued guidance and encouragement for AMDD.

David W. Powell
Chairman, American Medical Devices and Diagnostics Manufacturers' Association
(AMDD)
President, Johnson & Johnson K.K.
President, Johnson & Johnson K.K., Medical Company

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.

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

PAGE 2

The direction of medical care policy as seen in the medical fees revision

Medical service fees, after a review by the new government, were revised this April for the first time in 10 years. We asked Professor Yasuo Takagi, of the Graduate School of Keio University, Department of Health Management to explain the key points of this revision.

An ambitious additional revision – the first in 10 years

Net remuneration for the costs of medical service fees, including the portion for drug price reductions, was increased 0.19% as of April 2010. This was the first increase in ten years, since the 0.2% increase in 2000, showing the desire of the new political powers to revamp medical services in the present situation of medical care supply, in which some areas of medical care are collapsing.

Calculating the breadth of revision of medical service fees based on the 36,500 billion yen in medical service fees for the 2010 fiscal year, it shows an overall increase of 70 billion yen (0.19%). To accompany this, the state's contribution will be increased by 16 billion yen. Remuneration for medical service fees themselves is up by 1.55% (570 billion yen). Support for specific medical specialization service fees was increased by 1.74% (480 billion yen), with dental service fee support up by 2.09% (60 billion yen) and drug preparation fee support up by 0.52% (30 billion yen). The revisions included higher remuneration for hospitalization costs, up by 3.03% (420 billion yen), and an increase of 0.31% (40 billion yen) for outpatient fees.

Remuneration for acute care hospitalization medical service fees was also increased. As mentioned above, a major special feature of this revision of medical service fee support is the program for the revision of medical care by selection and concentration. The consultation document clearly stated that about 400 billion yen will be distributed to acute care hospitalization medical services. Drastic revision of distribution of medical care fees including fees for second or later visits, and the increase of hospital consultation fees, is aimed at improving emergency medical care, obstetrics, pediatrics, and surgery, by assigning high priority distribution of medical expenses to hospitalization medical care, emergency medical care and obstetrics. This differs from the previous distribution of medical expenses that favored medical practitioners/outpatients and was backed by the political power of the Japan Medical Association under the Liberal Democratic Party's political administration.

Increasing people's trust in, and maintaining, a health insurance system to cover all citizens

In September 2009, in the policy agreement by the coalition political administration of the Democratic Party of Japan, the Social Democratic Party, and the People's New Party, concerning medical care, it was decided that the special medical system for “old-old” patients was to be abolished, people's reliance on the national medical care system would be increased, and the health insurance system that covers all citizens would be maintained. The increased burden of the revenue gap caused by the loss of premium payments from persons who opt out of the national insurance system would be covered by the national government. The coalition administration would aim to maintain medical care expenses (as a GDP ratio) at a level similar to those of other advanced nations (OECD nations). Medical care expenses in Japan (GDP ratio, 2006) were 8.2%, far lower than the 15.3% of

the U.S., and the government wants to increase it to a level closer to France's 11.1% or Germany's 10.6%, even though this may take some time. The present revision increasing medical care expense payments can be considered a natural consequence of this policy.

However, in regional areas, strict and careful examination has been carried out regarding the revision of medical service fees for which official subsidies are provided, as embodied in the so-called “business classification and selection” screening process undertaken in the administrative reform working group meeting in November last year, which resulted in a portion of the financial resources being appropriated for measures to support doctors working in hospitals. The basic goal of this medical care policy is to stop the collapse of medical care without increasing the burden on patients. In other words, if the revision to increase medical service fees for hospitals and clinics were to be done using limited financial resources, the present situation would remain unchanged and it would not help resolve the shortage of doctors, so this revision of medical service fees was done so as to provide incentives for selected hospitals/clinical departments that are short of doctors, to encourage the redistribution of doctors according to the priority of the needs of hospitals/medical service departments/areas.

Eliminating the “cancer refugee” problem is another high- priority matter

Among the concrete medical service fee revision items, medical fee points for surgery which has a high level of difficulty, requires many assistants, and is mainly done in hospitals, have increased by 30-50%, and surgery-related medical fee points have been increased for roughly half of about 1,800 items, as an “appropriate evaluation of surgery.” The medical service fee evaluation system which has focused on the internal medicine system in terms of “doctors and drugs” has continued for a long time in Japan, but its revision is apparently being accelerated by the current changes.

In terms of the “evaluation of high quality medical treatment for cancer and the evaluation of cooperative treatment,” new points systems have been set up to evaluate medical treatment cooperative plans and the provision of careful explanations when patients leave hospital. For example, the cancer patient counseling fee is set at 500 points, the fee for setting up a cooperative cancer treatment plan (when a patient leaves hospital) is 750 points (for the hospital setting up the plan), and the cancer treatment cooperative plan guidance fee (cooperative medical organization) is 300 points (when information has been provided). This cooperation means that there will be selection and concentration with a cancer treatment cooperation base hospital as the axis, and can be said to be a program that will resolve the problem of “cancer refugees.”

Concerning the “appropriate evaluation of medical technologies other than surgery,” based on the studies of advanced medical treatment specialists’ meetings and medical technology evaluation work groups of special organizations for medical service fee investigation, fetal ultrasound echocardiography has been introduced to the insurance system, and its application to Intensity Modulated Radiation Therapy (IMRT) has been expanded. However, its further application to image diagnostic/treatment systems is desirable.

The social function of medical service fees is under scrutiny

On the reverse side of the coin of such technology evaluations and technology introductions, are the appropriate evaluation of medical materials/examinations based on current market prices and appropriate evaluation of technology that has less medical treatment effectiveness. In the present revision, remuneration for laboratory testing fees such as general examination of peripheral blood, ophthalmological examinations, and audiometry have been lowered.

As mentioned above, this revision of medical service fees has clearly shown a movement toward awareness of and the solution of medical care policy problems by appropriately evaluating valuable medical technologies that surpass previously-available technology, and will have notable effects. In the world of medical care, where the artisanal spirit of “my skills are the best” predominates, the question remains as to whether or not medical service fees should be determined according to the technical evaluation of medical care or the distribution of resources for lifestyle security. A balance between these two and the social function of medical fees must be determined.

Before the revision is made in the 2012 fiscal year, the influence of matters evaluated this time as having high priority will be verified, and the situation of the allotment of roles and changes to the content of medical treatment, will be investigated and verified after the evaluation of team medical treatments. Themes to be studied will also include the influence of the abolition of the adjustment coefficient for DPC and the introduction of function evaluation coefficients.

However, the greatest concern is by how much medical care expenses will be increased as a result of the current revision. This could settle within the estimated range of 2-3%, but if it results in a large increase of 4-5%, this would mean that the simultaneous revision of medical treatment and medical care insurance in fiscal 2012 will again become a political issue to be addressed. At present, in this situation of medical decay, we cannot talk about medical service fees without involving politics.

Mr. Yasuo Takagi, Professor, Department of Health Management, Graduate School,
Keio University

After graduation from Faculty of Education at Chiba University in 1973, Mr. Takagi joined the Japan Social Insurance Research Institute, and worked on "Ten-day reports on social insurance" in its editing department. Moved to the Special Corporation Social Security Research Institute in 1990, and became General Manager of its Research Department in 1993. After serving as a professor at Nihon Fukushi University and Kyushu University, he assumed present his post in 2005. His specialties are: medical care security theory, medical care policy theory, medical management theory, and geriatric care theory. He is author of many titles including "Doctor and patient economics", "Financial sources policy for social security," "Medical care expenses and medical care security," etc.

PAGE 3

Patient's Voice

Awaiting the establishment of a treatment to completely cure liver cancer

Mr. Takashi Akatsuka, Director and Secretary-General, Tokyo Kanzo Tomo no Kai (Tokyo Liver Patients' Network), NPO

“Kan-en Tomo No Kai” (Liver Patients' Network) was established in Japan in 1971 as a hepatitis patients' association. At that time, the causes of hepatitis were unknown, its diagnosis and treatment were not established, and the only treatment available was the taking of liver protection agents and herbal medicines. In those days, the type B hepatitis virus antigen was still called "Australia antigen", and hepatitis in many patients progressed to cirrhosis of the liver or liver cancer, taking their lives.

Later, the Type A and Type B viruses were identified, and in 1988, "non-A, non-B type" hepatitis was identified as Type C hepatitis with the discovery of the virus gene, and viral hepatitis diagnosis methods and treatments developed rapidly. Developments in blood chemical analysis, genetic engineering, and diagnostic imaging, brought about epochal advances in hepatitis treatment. Particularly notable was the establishment of interferon treatment, to which health insurance coverage became applicable in 1992, giving type C hepatitis patients great hope and the courage to live, since this treatment could eliminate the virus and achieve a complete cure. At present, the cure rate for type C hepatitis has exceeded 50% using pegylated interferon and rebetol combination therapy (standard treatment). The treatment for type B hepatitis is also advancing rapidly with the use of nucleic acid analog products.

Unfortunately, however, many patients with types B and C hepatitis have not yet been completely cured, and about 35,000 patients per year (120 patients every day) die after their hepatitis develops into cirrhosis of the liver or liver cancer. The treatment of hepatitis equals the prevention of liver cancer, meaning that not only blood tests but also diagnostic imaging are indispensable for monitoring the progress of hepatitis and for the early discovery of liver cancer. Advances in ultrasonic testing, CTs, and MRIs are contributing greatly to the prevention, early discovery and treatment of liver cancer. In the present situation in which no liver cancer treatment method providing a complete cure using drugs has been established, treatments such as radio frequency ablation treatment to remove liver cancer are contributing greatly to the progress of medical treatment technology.

Kan-en Tomo no Kai (“Liver Patients' Network”) groups have amalgamated to form the Nippon Kanzobyō Kanja Dantai Kyōgikai (“Council of Liver Disease Societies in Japan”), a nationwide organization with a membership of about 10,000. The Tokyo Kanzo Tomo no Kai group, an NPO started in 1990, now has about 3,500 members. This NPO receives telephone consultation calls from all over Japan and carries out activities to propagate and educate about hepatitis virus tests, holds lectures and meetings and issues bulletins, making efforts to widely propagate accurate knowledge about viral hepatitis and the latest treatments for it.

The aging of hepatitis patients and the increase in the number of serious cases are becoming more notable every year. A comprehensive hepatitis redress bill was enacted last year, so I am eagerly anticipating the completion of liver cancer prevention, prevention of the recurrence of liver cancer, and further progress in drastic treatments.

Medical Journalist Viewpoint

Preparation for the effective use of CT and MRI systems

Mr. Kazuo Maeno, editorial board member, Tokyo head office, Yomiuri Shinbun

Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) systems are widely known and symbolize the newest equipment. In daily conversation people say, “You'd better get a CT and an MRI test,” when someone has a minor headache or their heartbeat is a little fast, and people are relieved when they receive explanations of their diagnoses while being shown images on a computer. Reflecting such patient needs, expensive large diagnostic imaging equipment has spread even to small and medium-sized hospitals and clinics. As a matter of fact, the numbers of CT and MRI units installed per capita in Japan is the highest in the world.

Therefore, as a cause of increased medical expenses that was pointed out in the Fiscal System Council of the Ministry of Finance, it was noted that “regarding the numbers of expensive medical devices in Japan compared to European countries, Japan has 6-13 times more CT units, and 4-11 times more MRI units.”

It is certainly true that medical organizations in Japan have a great amount of CT and MRI units. The real problem however, is whether or not CT and MRI images are used appropriately for diagnoses. The quality of examinations differs greatly according to equipment performance and staff ability to read images. Regardless of whether equipment is the older or newest model, until now the medical service fee was the same, with or without personnel who are specialists in reading the images produced. Due to this, it is not strange that some medical institutes preferentially installed these systems first, and only later considered system performance and the maintaining of specialist staff.

Recently, high performance multi-slice model CTs, which can provide multiple images of different sectional positions with a one-time scan, have become mainstream. The number of slices varies from 2 channels to 320 channels, although nearly half of all CT systems in Japan still seem to be single-slice machines. Many MRI models in Japan have a magnetic flux density of 0.5 Tesla; only about 30% have magnetic flux densities of 1.5 Tesla or greater. According to a survey, 73% of CT machines in the U.S. have magnetic flux densities of 1 Tesla or greater, compared to only about 42% in Japan.

The shortage of specialist staff is more serious. There are very few medical specialists in diagnostic imaging in Japan compared to the numbers in North America and Europe. According to the Japan Radiological Society, 70% or more of institutions with MRIs and 80% or more of institutions with CTs have no diagnostic imaging medical specialists. The very limited number of medical specialists in diagnostic imaging is considered to connect to problems affecting diagnoses, including the adaptability of diagnostic imaging, the management of system precision, and the non-issuance of diagnostic reports. This lends validity to comments about this expensive equipment such as, “What a waste buying such expensive machines even though no one even knows how to use them.”

Such problems cannot be solved overnight, but a sloping distribution of medical service fees was adopted in the revisions of medical service fee in 2006 and after. This is based on facility standards such as equipment model performance and the provision of specialist staff. Appropriate operation of equipment and sufficient numbers of specialist staff members are indispensable for improving the quality of diagnostic imaging.

PAGE 4

First New Year's party since the inauguration of AMDD Held at the Imperial Hotel and attended by concerned persons

American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held its first New Year's party as a new association in the Imperial Hotel. AMDD was established in April last year when 62 medical devices companies with their head offices and sales bases in the U.S. became independent from the American Chamber of Commerce in Japan (ACCJ), Medical Devices and Diagnostics (MD&D) Sub-committee.

To begin, Chairman Huimin Wang of AMDD (at that time Representative Director & President of Edwards Lifesciences Ltd.) expressed his gratitude, saying, "Thanks to the kind support and cooperation from each concerned person in this gathering, AMDD has been able to greet the New Year in this way after just starting as an association."

Participants included guests from various sections concerned with medical devices, from, for example, the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), and from the Embassy of the United States of America in Japan, the ACCJ, The Japan Federation of Medical Devices Associations (JFMDA), and other medical devices industry associations in Japan, and patients' associations, in addition to representatives of member companies. At this gathering, opinions were actively exchanged concerning prospects for the medical devices industry in Japan.

The healthcare industry was previously considered strongly resistant to depression, but suffered great damage from the Lehman Shock in September 2008. Chairman Wang clarified his ambitious hopes in his greeting, "AMDD will work hard on major themes such as the revision of medical services even under the difficult economic situation, in order to carry out our role of providing advanced medical technology including medical devices for treatment, diagnostic imaging devices, and drugs for in-vitro diagnostics, to the actual sites of medical care in Japan, and will increase our activities for the benefit of Japanese patients."

In response to this, Mr. Hideto Sekino, Director of the Medical Devices Evaluation and Licensing Office, Evaluation and Licensing Division, Pharmaceuticals and Food Safety Bureau, Ministry of Health, Labour and Welfare said, "It is important that administrative agencies and industrial associations actively cooperate with each other for the introduction of better advanced medical devices." Mr. Takashi Wachi, Vice-Chairman of the Japan Federation of Medical Devices Association (JFMDA) added, "Deregulation of medical devices is always an important item on the agenda of the U.S.-Japan Business Council (USJBC) each year, and Jean-Luc Butel, Executive Vice President & Group President, International of US Medtronic, served as Chairman on the American side last year. This shows just how much of a major concern the U.S.-Japan problem regarding medical devices is now seen to be."

At the conclusion of the party, the customary *tejime* (clapping in unison) was led by Maulik Nanavaty, Chairman of the AMDD Membership Committee and President of Boston Scientific Japan K.K., with his best wishes for good progress this year for member companies and all the participants.

Value of Medical Technology (Orthopedic materials) Extending healthy life, starting with knees

The World Health Organization (WHO) now refers to the period of one's life in which one does not need care by another person, as our "healthy life expectancy", and is calling for the world to extend this.

However, it is estimated that more than 30 million people in Japan suffer from knee osteoarthritis, complaining mainly of pain and difficulty in walking. Over 7 million people per year choose artificial joint replacement surgery in order to overcome the obstacles of joint disease. The time to start considering artificial joint replacement surgery is said to be "when a person feels it is too much trouble to go out and walk to a place nearby to do some business, and when a person has started to encounter obstacles in their daily life." People with knee pain do not get enough exercise, resulting in a decline of muscular power or a tendency to grow fat, and they can easily fall into a vicious cycle in which the burden on their knees increases.

In artificial joint replacement surgery the cartilage and bone of the damaged joint are removed (see upper figure) and metal parts are implanted (see lower figure). A half century has passed since the first artificial joint was developed, and design/material quality/surgical techniques to increase the durability of artificial joints are advancing constantly. The effect of artificial joints in easing pain is great, and therefore many patients regretfully say, "I should have had the operation sooner." The earnest desire of manufacturers of artificial joints is to remove knee pain for many people and extend their "healthy life expectancy."

Asako Hashimoto, Stryker Japan K.K.

"Advocacy Committee" formed in AMDD

A new Advocacy committee was formed in AMDD in November 2009. Its duty is to report various proposals, critical concerns and information at directors' meetings and individual committees' meetings to stakeholders in all directions. This is necessary because innovations in new medical devices, in-vitro diagnostics, and medical technology, need to be recognized in the community and receive appropriate evaluation.

In order to provide detailed service and products that can respond to the needs of society, we must thoroughly discuss the medical care system in Japan with policy planners and associations concerned with medical treatment. We wish to contribute to creating an environment that makes it easy to introduce medical technology which improves the welfare and treatment of patients, by cooperating with the Public Awareness Committee, which transmits information to society.

We are already coordinating the points at issue in administrative body-private company dialogues, providing input concerning strategy for the growth of the medical devices field, and cooperating with business associations in Japan and overseas to accompany these activities. We sincerely hope for your cooperation.

Mitsunobu Sato, Chairman of AMDD Advocacy Committee
Director of Japan Healthcare Economics and Government Affairs,
Medtronic Japan Co., Ltd.