

# AMDD *Vol.7*

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## NEWSLETTER

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\*English translation of Japanese newsletter

### **CONTENTS**

- Chairman's Message Regarding the Great East Japan Earthquake
- The Proper Maintenance of Medical Devices is Indispensable for Diagnosis and Treatment
- My hope for Japan's healthcare system, the value of innovation
- Patients' Voices: Patients' problems transformed by advanced medical technology
- Medical Journalist Viewpoint: Technology and Safety Are Two Important Pillars of Healthcare

### **Chairman's Message Regarding the Great East Japan Earthquake**

On March 11, the Tohoku Region in northeastern Japan was hit by a devastating offshore earthquake and tsunami. We at AMDD would like to offer our deepest condolences and sympathy to the families of those who lost lives in this catastrophe. We have been deeply saddened by the continued suffering of the survivors who now have to contend with the loss of their homes and property, sheltering in uncomfortable surroundings in cold weather and the struggle to find missing family members, relatives and friends.

Many AMDD member companies have made cash donations and are now cooperating to provide much needed medical devices and diagnostic products to doctors in the affected areas. Moreover, we are working to ensure a stable supply of medical products to hospitals in these areas, despite the many logistical challenges.

We sincerely hope that everyone affected by this catastrophe will have the chance to recover and to once again lead safe and healthy lives as soon as possible. We will continue to cooperate with the administrative authorities and we will make every effort possible in assisting in the rehabilitation and reconstruction activities.

March 2011

David W. Powell

Chairman, American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

## **The Proper Maintenance of Medical Devices is Indispensable for Diagnosis and Treatment**

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) has submitted a proposal to the Ministry of Health, Labour and Welfare (MHLW) on the importance of complying with rules and regulations relating to medical device maintenance, including X-ray equipment. In this issue we talk to Dr. Takaaki Kameda, Chairman of the Board of Kameda Medical Center, about general safety controls of medical devices from the standpoint of a hospital operator, where they are making progressive efforts.

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Having originally commenced my career as a cardiac surgeon, I became familiar with numerous medical devices and recognized their importance long ago. As a matter of course, advanced medical devices are essential for fulfilling the role of main hospitals in sparsely populated local communities such as Kamogawa City in Chiba close to the southern edge of the Boso Peninsula.

At the beginning surgeons operated an artificial heart lung apparatus. In 1993 we employed two medical engineers (MEs), engineers specializing in medical devices, taking into consideration that surgeons would feel more assured when undertaking surgical procedures if they could leave the operation of the devices to the MEs. The MEs took charge of the handling of devices during operations in the department of cardiac surgery and neurosurgery and managed medical devices across the entire hospital. In the following year another two MEs were employed. They managed medical devices for high-pressure oxygen treatment and those in ICU. In 1985, an independent ME room was established.

### **Twenty-three years have passed since the introduction of clinical engineering technologists in Japan**

In 1988, the Clinical Engineers Act was enacted and a national qualification for clinical engineering technologists was established based on licensing. A clinical engineering technologist is defined as a person who operates and maintains life support and controlled devices under the direction of surgeons. In 1990, we secured the reliability and safety of the ME room expanding the area by six times (150m<sup>2</sup>) and increasing the number of engineers to 19. In the same year, we began operating the electronic medical chart system with the cooperation of surgeons and physicians.

Kameda Medical Center, comprising of Kameda General Hospital, Clinic and Rehabilitation Center, has around 1,000 beds. There are 880 inpatients, 2,930 outpatients per day and 70 emergency cases. Our staff comprises of 377 regular physicians and surgeons, 728 nurses and 550 healthcare providers working in teams for patients in medical care. MEs are included in healthcare providers and that number will soon be increased to 47.

The total number of medical devices at Kameda Medical Center is approximately 4,400, consisting of ECG monitors, automatic blood pressure meters, ultrasonic echo apparatuses, pulse oximeters, ECG, defibrillators, electrosurgical units, artificial respirators, infusion pumps and syringe pumps. Twelve MEs maintain and manage these medical devices at all

times. This is because unless all medical devices are operated safely, proper diagnosis and treatment will not be provided to patients and severe medical mishaps may result.

When the medical fee scheme was amended in 2008, the addition of 100 points (corresponding to 1,000 yen) was approved once a month as a Type 1 medical device safety control fee if any of the six types of designated medical devices were used for a patient, such as artificial heart lung apparatuses, artificial respirators and defibrillators. However, when we requested a maintenance management fee, while regarding an anesthesia apparatus mounted with an artificial respirator as being equivalent to an artificial respirator, it was rejected and the score was eventually halved. Based on these unreasonable circumstances, our hospital only earns around 1,060,000 yen a year from Type 1 medical device safety control fees. The actual personnel costs for MEs are hundreds of millions of yen per year. We actually put pressure on ourselves just because we want to provide our patients with the highest possible level of medical care.

### **Increase in productivity due to the involvement of clinical engineering technologists**

Work efficiency would be impaired and malpractices would certainly occur more often if a surgeon or nurse had to check medical devices every time they were used. Since employing MEs, productivity has increased, the physicians and surgeons are free to concentrate on diagnosis and treatments including surgical operations and the frequency of medical mishaps have declined.

The reported number of MEs working in medical institutes in Japan is about 16,000, although there are as many as 8,800 hospitals and 11,931 clinics around the country. It is thought that about 9,900 out of 16,000 MEs are engaged in dialysis. Accordingly, one or fewer MEs per institute take exclusive charge of medical equipment management. Such a state does not ensure the proper maintenance management of medical devices. This is an accurate account of the current state of affairs, although 23 years have passed since the clinical engineering technologist qualification system was launched. The same problem can be found in the field of radiological technologists. I believe that the government, medical institutes and medical device manufacturers need to commit themselves more seriously to the maintenance of medical devices.

Note: This is a summary of a talk given by Dr. Kameda at AMDD 19<sup>th</sup> Media Lecture, edited by the editorial desk.

Dr. Takaaki Kameda  
Chairman of the Board, Kameda Medical Center

Dr. Kameda graduated from the Faculty of Medicine, Nippon Medical School in 1978 and worked at Nippon Medical School Hospital after graduation. He graduated from the Graduate School of Medicine, Juntendo University (Department of General Thoracic Surgery) in 1983 and subsequently worked at Kameda Medical Center as a cardiovascular surgeon. He took up the office of chairman of the board at Tokyo Medical and Dental University from 2004 to 2008. Dr. Kameda has served as Chairman of the Board of Kameda Medical Center since 2008.

## **My hope for Japan's healthcare system, the value of innovation**

Japan presents a unique irony in its ability to innovate. Japan's success in innovation and continuous improvement in industries ranging from steel and automobiles to electronics, has been spectacular. According to the Harvard Business School (2009), Japan has produced remarkable developments in certain sectors but seems increasingly inadequate to do the same in modern technology industries.

PwC's Medical Technology Innovation Scorecard (2011), a new, multifaceted assessment of countries' ability to adapt to the changing nature of innovation, ranked the overall innovation capacity of nine countries: Brazil, China, France, Germany, India, Israel, Japan, the United Kingdom and the United States. Findings reveal that the U.S. currently holds its position as the global leader in medical technology innovation; and because of decades of innovation dominance, it continues to show the greatest capacity for medical technology innovation. Among the developed countries included in the study, Japan demonstrated the weakest support for innovation. China, in contrast, has shown the largest improvement in its medical technology innovation capacity during the past five years; and is expected to continue to outpace other countries and reach near parity with the developed nations of Europe by 2020.

Factors found to impact Japan's capacity for innovation include environmental and structural factors, such as hierarchical industry organizations which can simply "lock out" certain types of innovation indefinitely by perpetuating established business practices. Other accepted factors impacting this issue include the burden of clinical testing, the strict Pharmaceutical Affairs Act and even legal responsibility issues for government officials.

The innovation issue, if not remedied, has the potential to lead to a number of dangerous flow-on effects, including a decreasing ability to compete with innovations from lower-cost countries and a greater healthcare burden, in addition to its obvious impact on the Japanese economy.

The PwC Innovation Scorecard identified five broad "pillars" that helped to make the U.S. a leader in medical technology innovation for the past several decades: Powerful financial incentives such as reimbursements for adoption of new technologies; resources for innovation, such as academic medical centers; a supportive regulatory system; demanding and price-insensitive patients; and a supportive investment community of venture capitalists and other investors.

In my experience, in order to see innovation take place in Japan we therefore need the following:

1. A regulatory environment which supports innovation.
2. Regulations should only exist if they increase safety, enhance quality of life (QOL) and increase cost effectiveness. Other regulations increase delays in approval and funding and therefore availability of life-saving technologies to patients. A regulatory system which sees the Ministry of Health, Labour & Welfare (MHLW) reviewers held personally accountable for future product issues is specific to Japan and not productive.
3. A landscape which allows for a financial environment where people will be willing to invest.

4. A clinical environment which is less expensive and allows for proper indication to be given - today in Japan many indications are restricted.
5. A medical environment where younger physicians (who generally account for the majority of innovation) are given the freedom to innovate, which is not provided under the strict seniority system of today.

There are of course today a multitude of challenges facing the government as it tries to manage health care. Innovation in the medical industry and the investments that are needed for such industry is one of the best indicators for growth and high skilled job creation. Creating an environment where health is seen as an investment rather than a cost, will result in a more competitive, healthier and wealthier Japan.

Jean-Luc Butel  
Chairman, The U.S.-Japan Business Council  
Executive Vice President, Group President, International, Medtronic Inc.

## **Patient's Voice**

### **Patients' problems transformed by advanced medical technology**

By Ms. Kayo Umemoto

Chairperson of Akebono-kai – A patient group for Aortitis Syndrome

Aortitis syndrome is a rare intractable disease caused by stenosis, occlusion and the expansion of major blood vessels due to inflammation. The symptoms vary significantly depending on the location of the affected blood vessels and range from vertigo to postural hypotension, headache, angioalgia, angina pectoris, renal disorders, generalized fatigability and easy fatigability.

The disease is also called Takayasu disease, uncommonly named after a Japanese person. Two years ago a public symposium on Takayasu disease was held to commemorate the 100th anniversary since its discovery. I learned that the disease was initially left untreated and patients could not lift their heads because inflammation of the cervical artery hindered blood flow to the brain while blood vessels in the eyes were affected and blindness resulted. Many patients died young.

The disease remains intractable. However, two major changes have occurred since it was discovered. First, the medical condition is exacerbated less frequently than before as long as patients are put on immunosuppressive therapy, such as an oral administration of steroids.

Second, early diagnosis is possible today thanks to advancements such as diagnostic imaging systems. Some of our members were diagnosed as having early-stage aortitis syndrome after it was detected in a medical checkup. CT, MR and PET-CT scans have replaced catheter-based burdensome angiography for identifying the site of stenosis and as a result diagnosis became possible. Contrast media and catheters for angiography have also advanced. I have learned from my experience that such advancements have contributed to a drastic reduction in the burden experienced by patients.

In addition, the images that can be obtained are clearer. I believe that more patients are diagnosed at a stage of minor stenosis; that is before they notice they have the disease. Many patients with aortitis syndrome lack awareness of the disease and do not rest due to the symptoms. In my experience, more patients are seeking advice regarding how to live with the disease, for example, how to work and fall pregnant. Some are not happy with the use of steroids when they are asymptomatic.

Today, there are lower-risk treatments for valvular insufficiency and stenosed blood vessels thanks to the evolution of artificial cardiac valves, balloons, stents and catheters. Some patients undergo intravascular treatment and become free from stenosis without ever experiencing the symptoms of such a serious disease. This may be one of the reasons why patients seek a quality of life (QOL) equivalent to that of healthy people.

However, even after blood flow in arteries is corrected, patients inevitably suffer from persistent fatigue and easy fatigability and have difficulty leading lives like those of other healthy people while on several kinds of medicine. In fact, there are some patients who continue to face critical conditions. I really hope that a cure will be discovered as soon as possible.

## **Medical Journalist Viewpoint**

### **Technology and Safety Are Two Important Pillars of Healthcare**

By Mr. Akira Ogawa

Senior feature writer, editorial writer, Kyodo News

How should we view the advancement of technology and secure its safety? This is becoming an ever more momentous challenge in health care that is subject to rapidly progressing technological innovations. I affirmed this concept after observing a series of court judgments that were punitive toward a pharmaceutical company in case associated with Iressa, the therapeutic drug for lung cancer.

Compared with healthcare practices thirty years ago, the development of medical devices is astonishing. I remember being impressed by the then newly developed computerized tomography (CT) when I started working as a journalist in 1975. At that time, however, I did not expect such improvements in CTs and MRIs and their subsequent proliferation. Technology has become more and more innovative with breakthroughs in terms of principles. I am convinced that this is one reason why postmortems have decreased when looking at images using the most advanced device that show organs in the body clearly and in three-dimension.

People's ceaseless desire for life serves as the driving force for growth in a mature society that is oriented toward wellness. The successive introduction of new medical devices has been a huge benefit to humans. In Japan, imported medical devices occupy a large market share. Among the players, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) enjoys a strong presence with a 60% share of the Japanese market as a result of undertaking proactive PR activities.

At the AMDD media lecture in February, the maintenance management of medical devices was carefully explained, from which I learned a lot. Patient lives are at risk if there is something wrong with them including life support systems such as artificial respirators, cardioverter defibrillators and infusion pumps. Maintenance management appears to be insufficient as far as contrast medium injectors and ultrasonic apparatuses are concerned. I was also informed that the level of maintenance differs by medical institute and that the management is unsatisfactorily performed in reality.

Malpractice is often accompanied by a failure of the apparatuses or its incorrect operation. Having been running *Kyodo-kodo*, a public health safety campaign, since it started in 2008, the campaign consists of nine behavioral objectives, one of which is to ensure the safe operation and management of medical devices. The Japan Association for Clinical Engineering Technologists participates proactively in the campaign. The latest safety measures are required everyday as technology advances. Among this field, related parties need to cooperate appropriately with each other, such as physicians, nurses, radiologists, clinical engineering technologists, medical device manufacturers and industry groups. To prevent accidents, even patients need to know the risks associated with medical devices.

In 1999, medical mishaps were uncovered one after another. This helped raise awareness of medical safety. Subsequently, confusion arose as criminal investigations were undertaken into medical accidents. Today the situation has almost dissipated, however it is time for medical professional groups and institutes to construct a system of medical safety for patients. Japan is in the midst of a major hardship caused by the earthquake and tsunami. I hope to be able to support the areas affected with medical care for the long term.

#### **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.