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NEWSLETTER

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English translation of Japanese newsletter

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AMDD Becomes a General Incorporated Association on its 7th Anniversary

I would like to provide a New Year's greeting for 2016 on behalf of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD).

AMDD was established as an independent body in 2009 to continue the industry activities previously undertaken by the Medical Devices and Diagnostics Subcommittee of the American Chamber of Commerce in Japan (ACCJ). Since then, we have been engaging in activities that seek to provide patients, medical practitioners, and others in Japan with advanced medical technologies that comply with international standards. Specifically, this has included working with various other organizations on overcoming the issue of "device lag", and encouraging the establishment of a regulatory framework that is appropriate to medical devices. Along with shortening the time taken for the approval of medical devices, we are also delighted that this has led to the introduction of the Pharmaceuticals and Medical Device Act, something that we had pursued for a long time, which was passed in November 2013 and took effect from November 2014. This is an opportunity for a major leap forward by the medical device industry in Japan.

AMDD entering a new stage

AMDD will celebrate its seventh anniversary in 2016. This year will be a milestone for us, marking a new stage in our career as we become an "ippan shadan hojin" (general incorporated association), enabling us to make an even greater contribution to Japanese healthcare. We have chosen to take this step in the belief that restructuring in this way will improve transparency and confidence in us as an organization, while enabling us to make an even greater contribution to medicine and healthcare in Japan.

Medical devices and in-vitro diagnostics (IVD) are utilized in a wide variety of ways that extend beyond the treatment of illness, such as prevention and achieving a better post-treatment prognosis. As an industry body that provides such medical devices and IVDs to patients in Japan, we are dedicated to our new mission and in further expanding the scope of our activities. We have decided on a new mission statement for AMDD; "Providing valuable medical technology and information to your loved ones today, so that they may live in good health."

Future tasks of the AMDD

With the medical device industry acknowledged as playing a role in national strategy, and at the AMDD, we have also been making proactive efforts to build relationships with local governments that are seeking growth through manufacturing. As an association rooted in this country, the AMDD will continue to further strengthen its cooperation with the Japanese government, administration, and related bodies to promote the growth of the medical device industry in Japan.

In order for innovation to accelerate, a system that can properly evaluate and nurture innovation is necessary. To enable the provision of valuable medical technology and information to patients within constrained healthcare budgets, we will lobby for the establishment of a better regulatory environment.

Furthermore, it is essential to have a global perspective in order for the Japanese medical device industry to grow. The scale of the Japanese medical device industry is about one-tenth that of the global industry. We need to keep an eye on the global market to expand the industry scale. For this purpose, regulations must be consistent with global standards. At the AMDD, we will engage in dialogue with the government to ensure that the PMD Act is administered appropriately

AMDD intends to continue making a contribution to the development of Japanese healthcare through its activities in collaboration with the Japanese administration, medical societies, and related industry associations, while also maintaining close relationships with the with the U.S. Government and the U.S.-based Advanced Medical Technology Association (AdvaMed). We look forward to your ongoing recommendations and support for the AMDD.

We at the AMDD would appreciate your continued guidance and support this year.

Kosuke Kato
American Medical Devices and Diagnostics Manufacturers' Association (AMDD)
Managing Director,
Edwards Lifesciences Corporation

The Dr. Gon System – Home Care on an Island and in the City

Critical care physician turned home health physician

I was born on Miyako Island. At that time, Okinawa was still governed by the U.S. I moved to Okinawa Island before I can remember and entered elementary school. When I was in the first grade, I moved to Edinburgh, Scotland due to my father's work as a physician. I lived there for 2 years, and after returning to Japan, I entered a medical school in Tokyo. After graduating, I pursued a career in critical care and led a busy life in the Department of Critical Care and Emergency Medicine at the Tokyo Women's Medical University.

I believed that this place was the last resort for saving critically ill patients, and I was reminding myself every day that I should not give up even in the hardest situation. Giving up means the "death" of a patient, which in turn means a "loss" for a critical care physician. However, I suddenly felt emptiness. I made every effort to save patient lives, but they were not conscious and their life was just being sustained by an artificial respirator. There were so many patients who had completely changed from the vibrant people they had been before.

I started asking myself whether saving a life in a medical sense might not be the same as saving a person in a real sense. Ultimately, I recognized the importance of "just being by a patient's bedside at the end of his or her life" and started pursuing home health.

Characteristics of home healthcare in remote islands

In 1997, I left the front line of critical care and moved back to my home town, Miyako Island, to start home care. In 2000, I opened Dr. GON Clinic. I opened another clinic in Kamakura in 2004. Since then, I have been commuting between Miyako Island and Kamakura at weekly intervals for the past 10 years.

Miyako Island is a relatively big island with a circumference of about 100 km and a population of about 55,000. There are also small islands such as Irabu Island and Ikema Island around Miyako Island. There are four hospitals (one of them is for Hansen's disease) in Miyako Island.

I usually use a car or ship to visit a patient's home, but also use a jet ski. The average speed of a jet ski is about 70 km an hour. It takes 2 hours to go to Ogami Island by ship, while it takes only 45 minutes by jet ski.

The clinic and patient's home are connected by an electronic medical record. I built a network system called Dr. GON, which connects the clinic to home-visit nursing stations, nursing care centers, dispensing pharmacies, and the patient's home. This system is convenient: when I visit a patient's home and write a medical record, the record is sent to the clinic in real time, and by faxing it to a dispensing pharmacy, the medicine can be prepared quickly. When I visit a patient's home, I bring with me a notebook computer on which this system is installed.

What kind of patients are there on the island? One of the characteristics is that we have patients with rare diseases or infections becuase they are living under circumstances or situations completely different from that of urban areas.

For example, I saw an elderly male patient with shortened fingers. I could not recognize the disease at first, but it was untreated Hansen's disease.

Hansen's disease develops in only about four people per year in Japan, but I have met three untreated patients during my 17-year practice in Miyako Island. This patient recovered from Hansen's disease with the help of a drug prescribed by us, and passed away from old age.

I also saw an elderly woman who turned on a stove on a hot day in August, and it caused her foot to swell due to a low-temperature burn. She was taken to hospital and told that she

would have to have her foot amputated, but she consistently refused. After she returned home, we took charge of her treatment. Her injury was almost completely healed by debridement.
There are also cases that cannot be resolved only by healthcare. In a house where an elderly, mentally handicapped elder sister and younger brother were living, the sister had diarrhea. When I visited their home, I found that they were using collected water because they did not have running water, and their sanitary conditions were very poor. Therefore, with cooperation from their neighbors, I helped them gain access to water free-of-charge.

Important points for healthcare in remote islands

To follow patients in such a wide variety of cases, not only healthcare but also welfare is necessary. A network connecting healthcare, elderly care, and nursing care is essential.
Practicing healthcare in remote islands is extremely hard work. I do not want people to come to the island and say "I will work for only three years." In remote islands, it is important to provide healthcare in a stable and continuous manner. To achieve this, we must fit in with the local community and build a foundation that allows us to live comfortably. We must avoid wars of attrition that use up all of our physical and mental strength.
Sometimes people ask me, "What is your area of specialization?" and I answer, "I am a specialist of life." Making every effort to save life and just being by a patient's bedside at the end of his or her life appear to be complete opposites, but they are actually two sides of the same coin that deal with the same thing, that is, life. I will continue to work as a physician who explores life.

*The article was summarized by the editorial department based on a lecture given by Dr. Yasukawa.

Dr. Keigo Yasukawa
Toriden Shirakawa Medical Corporation
President (Dr. GON Clinic, Dr. GON Kamakura Clinic, small and multi-functional nursing care service GON)

Born on Miyako Island, Dr. Keigo Yasukawa lived in Scotland for 2 years in his childhood. Dr. Yasukawa graduated from the School of Medicine, Kyorin University in 1989. He joined the Second Department of Surgery, Tokyo Women's Medical University. Dr. Yasukawa started working in the Department of Critical Care and Emergency Medicine in 1992. He returned to Miyako Island in 1997 and opened a clinic. Dr. Yasukawa opened a second clinic in Kamakura in 2004. He is currently President of Toriden Shirakawa Medical Corporation.

Patient's Voice
Expectations and Challenges for a New Blood Glucose Meter

Eiichi Ohmura
Executive Director,
Approved Specified Nonprofit Corporation Japan IDDM Network

I developed type 1 diabetes mellitus 21 years ago. My body cannot secrete insulin, which allows glucose to be taken up into cells. Therefore, I must supplement insulin by giving myself daily injections.

The hardest part of this disease is that I have to control my blood glucose level myself (the concentration of glucose in my blood). It used to be automatically controlled by my body before I developed the disease. For this control of blood glucose level, it is necessary to carry out self-monitoring of blood glucose (SMBG) to measure the current blood glucose level. SMBG is basically conducted at the time of insulin replacement (about four times a day on average), and it used to be very difficult to know how my blood glucose level was changing when it was not being monitored.

Continuous glucose monitoring (CGM) was developed to resolve this issue. CGM simulates changes in blood glucose by placing a sensor with a needle subcutaneously in the arm or abdomen. It measures the glucose level in subcutaneous tissues, which has been associated with blood glucose level, every five minutes. This has made it possible to track changes in blood glucose by looking at lines on a graph, not points. But there is still a problem: values measured by CGM can only be checked in a medical institution at a later date.

The "Personal CGM," which has been covered by insurance since April 2015, is now attracting attention as it may resolve this issue. With the Personal CGM, the blood glucose level measured by CGM can be checked promptly using a monitor. It is provided in a system called sensor augmented pump (SAP) integrated with an insulin pump (a small device that can program the amount of insulin to be injected). Unlike conventional CGMs that have been controlled by medical institutions, this system allows patients to change the amount of insulin and manage dietary and exercise activities by checking their blood glucose level on a monitor.

Overseas studies have already shown that patients who continuously use SAP maintained more favorable blood glucose control. I highly expect that this will help patients who have tried treatment but failed due to their constitution or complications as well as pregnant women who require careful control.

SAP is expected to reduce the risk of complications and cut the medical cost required for diabetes treatment in the future. However, many patients have not been able to switch to SAP because it costs more than twice, or nearly three times in some patients, the amount of conventional treatment. Since type 1 diabetes mellitus is a disease specified in the Research into Treatment for Specific Child Chronic Diseases, underage patients can use SAP with the support of public expenses. However, some of them may switch back to conventional treatment as soon as they turn twenty. We would like to ask for public aid in

medical expense based on the results of a currently conducted national epidemiological survey.

Japan IDDM Network http://japan-iddm.net/ (Japanese)

Voice from the Local Government
Development of Medical Devices in Kobe Biomedical Innovation Cluster (Part 2)

Masao Imanishi
Chief Operating Officer,
Kobe City
(in charge of Kobe Biomedical Innovation Center and Kobe Enterprise Promotion Bureau)

(Continued from the previous issue)

3. Efforts to support the development of medical devices

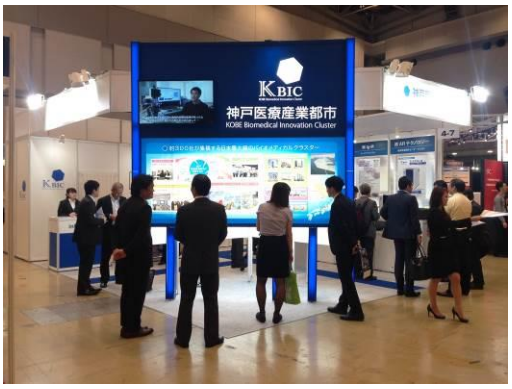
In the Kobe Biomedical Innovation Cluster, Kobe City and the "Foundation for Biomedical Research and Innovation," which is an external body founded by Kobe City to advance the biomedical innovation cluster vision, is taking the initiative to support companies in the development of medical devices. In recent years, an increasing number of companies have aimed to enter the medical device industry from different business fields such as the automobile and home appliance industries. This necessitates consistent and generous assistance from entry to exit, that is, matching needs and seeds to marketing.

For this reason, the Kobe Biomedical Innovation Cluster promotes the program "Platform for Acceleration of Commercialization of Medical Devices". It provides companies that have excellent technological seeds for medical devices with total assistance at each stage of commercialization. Such stages include matching needs in medical practice, planning commercialization strategies, composing development companies, producing prototypes, developing marketing strategies, developing marketing routes, and conducting marketing and training of physicians with the cooperation of clinicians and other experienced professionals. This program has been utilized by many companies, and some of them have already succeeded in commercializing products. We also provide opportunities to run a joint booth in exhibitions held in the Tokyo metropolitan area and overseas (such as Germany and Thailand) to support the development of new marketing routes and discovering partner companies.

City and foundation staff carefully elicit demands from companies on a routine basis. This allows them to provide rapid and appropriate assistance such as matching companies with academia or other businesses that have the necessary technology, and supporting compliance with various regulations including the Pharmaceutical and Medical Device Act.

In addition, the Kobe Biomedical Innovation Cluster hosts a "cluster networking event" every month, which consists of special lectures by leading experts in different fields and introducing technologies by entry companies. This event gathers about 100 to 150 participants at every event and has earned a positive reputation.
Furthermore, many Japanese and non-Japanese companies are developing medical devices using the "Kobe Medical Device Development Center (MEDDEC)." This center is the only public facility in Japan which allows physicians to be trained in surgical procedures using live pigs in an operation room. Procedures include training, research and development, and the evaluation of medical devices such as catheters, stents, and implants.

4. Aiming to be the "best biomedical cluster in Asia"
The Kobe Biomedical Innovation Cluster has grown by promoting proactively collaboration within the cluster and supporting the commercialization of products developed by medical device development companies. At the same time, it has facilitated the accumulation of academic-industrial cooperation hubs for basic research, highly specialized hospitals, and healthcare-related companies into clusters. We will continue to support companies in the commercialization of products, with the aim of forming the "best biomedical cluster in Asia."



Left: Exhibition
Right: Cluster networking event

7th Annual New Year's Party

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held its 7th New Year's celebration party on January 15, 2016. In the opening speech, Kosuke Kato (Managing Director of Edwards Lifesciences Corporation), Chairman of the AMDD, welcomed the increased visibility of the term "medical device" due to revisions in the Pharmaceutical Affairs Law and its name change. He also stated that the AMDD became a general incorporated association this January and introduced its new mission. He expressed hope saying, "I would like to cooperate in making Japanese society better, from diagnosis and treatment to innovation, by making use of our position as a Japanese incorporated association."
Aftewards, guests Mr. Yuzuru Takeuchi, Senior Vice Minister of Health, Labour and Welfare, and Hiromi Mitsubayashi, Parliamentary Vice-Minister of Health, Labour and

Welfare, expressed their expectations saying "the medical device industry is an important industry that supports the economic growth of Japan." Mr. Steven Anderson, Senior Commercial Attaché for the U.S. Embassy stressed that he would like to strengthen the relationship further. Mr. Koji Nakao, Chairman of the Japan Federation of Medical Devices Associations, said "I would like to continue our mutual cooperation this year, including from the perspectives of the public." Mr. Kennichi Matsumoto, Chairman of the Japan Association of Medical Devices Industries, made a toast. After the toast, participants celebrated the New Year with guests from various sectors such as the Ministry of Health, Labour and Welfare, PMDA and medical device associations.

Left: Mr. Kosuke Kato, Chairman, AMDD
Right: The 7th New Year's celebration party

AMDD Becomes a General Incorporated Association

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) was registered as a general incorporated association on January 4, 2016, and is now the "General Incorporated Association American Medical Devices and Diagnostics Manufacturers' Association."
In line with this change, we renewed our mission and added the tagline under the AMDD logo, "Enabling a Healthier Japan." Japan was added to the tagline with the aim leveraging our position as a Japanese incorporated association and our work for Japan.
We will continue advancing our activities deeply rooted in Japan by fulfilling our new mission, "Providing valuable medical technology and information to your loved ones today, so that they may live in good health."

New logo with tagline

Value of Medical Technology < Cancer >
Cervical Cancer Cytology

The morbidity and mortality of cervical cancer have been increasing in Japan, especially among young people in their 20s or 30s. The main cause of cervical cancer has been found to be infection with human papillomavirus (HPV).

Test methods for cervical cancer include cytology and HPV gene test. For cytology, an increasing number of facilities have recently introduced liquid based cytology (LBC), which is expected to reduce inadequate specimens and improve accuracy, instead of the conventional direct smear method (direct application of samples to slides).

Some LBC methods can efficiently collect the necessary cell populations for diagnosis by suspending collected samples in a special medium to reduce red blood cells, mucus and other components selectively using isolation reagents. In addition, the use of fully automated systems for dispensing or pretreating samples and preparing specimens will further improve operability. Furthermore, samples collected by LBC can also be used for an HPV gene test.

Inadequate specimens may lead to misjudgments or retesting, imposing a significant burden on patients.

Cervical cancer can be early detected by a health check. The widespread use of LBC is strongly desirable to protect women from cervical cancer.

(Article written with full responsibility by Yoko Mukai, Nippon Becton Dickinson Company, Ltd.)

Fully automated slide preparation system for cytology

AMDD 5th Joint Media Seminar with JACRI
-Front line of home healthcare: Dr. GON system in remote islands and urban areas-

The Japan Association of Clinical Reagents Industries (JACRI)/American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held its 5th joint media seminar on October 1, 2015. In this seminar, we invited Dr. Keigo Yasukawa, or Dr. GON, who practices home healthcare by commuting between Miyako Island in Okinawa and Kamakura, to provide a lecture about the current status of healthcare in Miyako Island and its neighboring islands, and the reality of end-of-life care at home under the theme "Front line of home healthcare: Dr. GON system in remote islands and urban areas."

In the opening speech, Mr. Haruyoshi Sakamoto (Representative Director and Chairman of the Board and President of Abbott Japan Co., Ltd.), Director of the AMDD, stated that there is an urgent need for home healthcare and nursing care in this aging society. He also said that 70% of citizens have a desire for home care according to a survey conducted by the Ministry of Health, Labour and Welfare and we must steadily advance discussion to establish a healthcare system for this purpose. In the back of the seminar hall, IVD-related

devices used in home healthcare or visiting care were displayed. Many media listened to explanations about small portable test devices with interest.

(See page 2 for summaries of the lecture by Dr. Yasukawa)

The 5th JACRI/AMDD joint seminar

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.