

AMDD *Vol.33*

NEWSLETTER

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Greetings from the New Chairperson

It is an honor to have recently been appointed the 5th Chairperson of the American Medical Devices and Diagnostics Manufacturers' Association, an industrial organization composed of about 70 Japanese companies headquartered in the US that provide advanced medical technology such as medical devices and in-vitro diagnostics (IVDs). Since our founding in April 2009, our activities strive to meet the needs of patients in Japanese medical facilities and deliver the latest treatments, diagnostic technologies, and information under a theme of improving citizens' health and quality of life. Speaking personally, AMDD's social responsibility is a source of great motivation and lies at the heart of what we do.

Working Toward Good Health for Your Loved Ones

It is important for patients in Japan to have access to the same innovative medical devices used around the world. A long-standing focus for AMDD has been the "device lag" issue. Working closely with the Ministry of Health, Labor, and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA), and other organizations, we have been able to reduce approval times for medical devices, resolving most of the device lag. The Pharmaceuticals and Medical Device Act (passed in November 2013 and implemented the following year), separated regulations for pharmaceuticals and medical devices, and has paved the way for a major leap forward in the medical devices industry from the perspective of building a regulatory framework to better meet the characteristics of medical devices.

AMDD became a general incorporated association in 2016 in recognition of its social responsibility. To mark this change, we established a new mission statement: "Providing valuable medical technology and information to your loved ones today, so that they may live in good health." Medical devices and IVDs are used in a wide variety of ways that extend beyond treating illnesses, including preventive care and improving post-treatment conditions. In order to be an industrial organization that delivers such medical devices and IVDs to Japanese patients as promptly as possible, we have been further expanding the scope of our activities in line with this mission.

In order to promote the value of innovation in medical devices and IVDs, we have been recommending a policy of "value-based

healthcare" since 2017. Part of this recommendation has already been registered as a "Challenge Application." We have now established the AMDD Medical Technology Policy Institute think-tank within our organization in order to research ways for medical technologies such as medical devices and IVDs to contribute further to healthcare in Japan from the medium to long-term perspective, and to recommend policies based on this.

Contributing to Healthcare for Japan's Super-aging Society

Japan continues to become a super-aged society. The quick introduction and appropriate use of advanced medical technologies that are standard overseas will prevent the progression of illnesses and improve patients' quality of life, which will result in a longer life expectancy. A healthcare system that improves the health of society by appropriately evaluating and reflecting the value of innovative medical technologies will be important to achieve this. We need to consider the management and distribution of medical devices and IVDs, as well as the use of digital technologies in healthcare.

AMDD will continue to leverage its unique strengths as an industrial organization in the healthcare field to drive policy recommendations and make other efforts to support the positive development of Japan's healthcare system by collaborating with the Japanese government, medical societies, and associated industry associations, while also maintaining close relationships with the US government and the US-based Advanced Medical Technology Association (AdvaMed).

Kazuya Ogawa

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

Chairman and President,
Zimmer Biomet G.K.



All opinions in the newsletter are the views of the authors and do not represent the views of AMDD or its activities.

Patient Participation in Healthcare and Shared Decision Making (SDM)

A New Doctor-Patient Relationship

The relationship between doctors and patients is as much an old issue as it is new. Conventionally it has followed the informed model and paternalism, in which patients do what the doctors decide. Dating back to the 1980s, this model saw widely adoption as a precursor to informed consent (IC), whereby doctors provide information but leave the final decision on treatment method to patients. However, this is can be problematic for patients with limited medical knowledge.

Thus, the concept of Shared Decision Making (SDM) was born. SDM is a process in which medical professionals and patients collaborate to determine the best treatment method. In this model, both the doctors and the patients provide information about issues and concerns that are important to them. They then discuss the issues and decide the treatment method together.

The main advantages of this approach are better patient satisfaction with their experience, improved quality of life and treatment results, shorter hospitalization periods, and reduced healthcare costs. For medical professionals too, SDM brings advantages in reduced levels of burnout and fewer people quitting their medical jobs.

Shared Decision Making (SDM)

- A communication process in which medical professionals and patients collaborate to determine the best treatment methods for the patients in line with what is most important to the patients.
- SDM's three requirements:
 - Clear, accurate, and unbiased medical information on the available options (including not treating the condition), and the benefits and risks of these options
 - Medical professionals with specialist skill for communicating this evidence to individual patients
 - Information on patients' values, objectives, intentions, and concerns (including the burden of treatment)

Developed by the NQP (National Quality Partners) Shared Decision Making Action Team.

Working Toward Patient Well-being

I specialize in kidney disease, for which it is important that patients play an active role in deciding their treatment method. These decisions, such as whether to perform a kidney transplant or have dialysis treatment at home or the hospital have very real consequences for the patient's quality of life.

For example, let's consider patients with end-stage renal failure who have chosen hemodialysis. Patients often go down this route because it's the most common option. However, a variety of issues may arise once dialysis starts. There are cases when patients can't handle the needles, or

going into hospital three times a week is not compatible with their work. A patient good at operating machinery and managing themselves may be better suited to peritoneal dialysis. SDM allows patients and doctors to have more detailed discussions beforehand to prevent such scenarios where the treatment method doesn't match the patient's needs.

SDM is not only necessary at the stage of choosing treatment, but also when reviewing the resulting impact on life and potential recovery – particularly for treatments that place burden on the patient, and diseases such as cancer, chronic diseases, and renal replacement treatments.

Promoting SDM in the first instance must also involve patients. It is important we change the awareness and behavior of those patients who want to leave everything up to the doctor. In return, doctors must precisely convey the information patients most need out of a huge array of medical information. An honest approach is required in the discussion process to draw out the patient's true feelings.

In this approach, there is a limit to what doctors alone can do, so it is important to use team healthcare. There are decision-making support tools for promoting SDM, and the Japan Shared Decision Making Collaborative for Chronic Kidney Disease also conducts SDM training that uses role-playing in which medical professionals play the roles of patients and families.

Atul Gawande, a professor at Harvard University Medical School, has stated that the objective of medicine is to make well-being possible. He says that well-being means health and happiness (philosophically, "being well"), but that the ultimate objective of medicine is to support patients so they can live the life they want to live. SDM is truly a concept that makes well-being possible, and I would sincerely like to promote the adoption of SDM to help patients achieve well-being.

Yasuhiro Komatsu

Doctor, Master of Public Health (MPH), Doctor of Medicine Professor and Chairman at Department of Healthcare Quality and Safety, Gunma University, Graduate School of Medicine

Graduated from the Chiba University School of Medicine in 1984 and graduated from the University of North Carolina at Chapel Hill School of Public Health in the US in 2010. Has worked at St. Luke's International Hospital since 2017 as the Vice President and Head of Nephrology, and is involved with the quality and safety in healthcare and training at the university overall. He specializes in the dialysis field.





Kazutaka Mochizuki

Dystonian Friends Association (non-profit organization)
Director and IT Division Manager

Understanding Dystonia and its Optimal Treatments

Dystonia is a refractory disease in which muscles continuously or involuntarily contract and harden. Patients become stiff in unnatural postures, and they may become unable to stop muscles moving by themselves, restricting everyday life and bringing psychological distress. The cause is believed to be impairments in the brain or nervous system, but the disease does not affect intelligence or threaten the patient's life.

According to the Japan Intractable Diseases Information Center, there are approximately 20,000 dystonia patients in Japan. Due to its rarity and low rate of prevalence (only a few people out of every 10,000), there is a lack of medical specialists and information on the disease. Doctors often see cases where patients have had no choice but to travel long distances in order to find a hospital.

Patients and doctors established the Dystonian Friends Association in 2005 to deepen the understanding of this lesser-known disease, and have been working with related facilities to improve patients' experience with opportunities to cooperate and exchange information with each other. After putting requests to the Ministry of Health, Labor, and Welfare since 2008, a major win came in 2015 when hereditary dystonia became eligible for healthcare cost assistance for designated intractable diseases.

Common treatment methods for dystonia are drugs taken internally, localized injection treatments of botulinum toxin, and surgical treatments (stereotactic neurosurgery such as deep-brain stimulation (DBS) treatment and deep-brain lesioning procedures). Treatment with drugs taken internally and localized injection treatments are symptomatic treatments. There is a relatively high number of doctors that can perform DBS, which is a type of stereotactic

neurosurgery, and is said to have a high level of safety. However, as a treatment method that implants a device into the body, DBS may require periodic surgery to fix device degradation or replace batteries, bringing about significant physical and financial burden on patients.

Similarly, lesioning (coagulation) procedures are a type of stereotactic neurosurgery. These can be the fundamental treatment because they directly destroy the brain tissue that is producing the abnormalities. There are some examples in which coagulation procedures significantly improve symptoms, but there are few doctors or medical institutions that can perform the surgery, and recently the medical instruments necessary for the coagulation procedures have stopped being sold. This creates a serious issue for patients who are eager for a fundamental treatment but may not be able to access it. Similarly, although it's not necessary to cut a hole in the skull as some coagulation procedures use ultrasonic waves, the only area possible for lesioning is the thalamus, which depending on the shape of the individual's skull may make the treatment unsuitable.

The optimal treatment method could be symptomatic, DBS, or coagulation as a fundamental treatment, but ultimately depends on the patient's symptoms and lifestyle. We will continue to work on activities in the future that enable patients to choose their preferred treatment.

Dystonian Friends Association
(non-profit organization)
<https://www.dystonia2005.com/>



Supporting patients with a
clinical team

No. 4

Radiological Technologists

Mikio Sano

Vice President, Japan Association of Radiological Technologists



Healthcare is becoming more sophisticated and complex. Team healthcare is collaborative healthcare that leverages diverse occupations with high levels of specialization, shares objectives and information, and provides safe healthcare. By dividing work roles and encouraging workers to cooperate, members can complement each other. With patient needs also diversifying, there is a move toward emphasizing patient quality of life and creating a system that can provide ongoing, comprehensive care for the physical and mental health of patients, not just improved knowledge and technology for specialist occupations. We are truly facing an aging society, and healthcare is rapidly changing from diagnosing and treating illnesses to preventative medicine. As a specialist occupation that involves radiological imaging diagnosis and treatment, it is important to provide accurate and precise information to patients about less-invasive procedures.

In recent years, IT for healthcare has continued to evolve. Many healthcare facilities have digitalized their medical records and have introduced Picture Archiving and Communication Systems (PACS), which has made it possible to manage medical images in a centralized manner, and this has completely changed the content of work in clinical facilities. In

radiology departments, the digitalization of radiological devices has brought about technological innovations and led to the development of sophisticated medical devices. As a specialist occupation for new imaging information, new methods of managing images inside hospitals and cutting-edge testing technology continue to emerge, and new types of work have begun to develop in clinical facilities, such as building 3D images and navigation to support surgery.

Since radiologic technologists are the only ones who conduct X-rays, I felt it may have been too narrow a specialty to join team healthcare. However, in the routine testing work, there are many areas where doctors, nurses, and other medical staff members collaborate, and the staff members need to communicate with each other. For things like angiography tests and X-ray TV tests in particular, it is important to manage the medical radiation that patients and medical practitioners are exposed to from radiologic technologists.

It is predicted that clinical facilities will adopt AI and robots in the future, changing the way we work. But doctors and staff from other specialist disciplines will still need to collaborate. It is my hope that integrating my specialism in team healthcare will improve the safety and quality of healthcare for patients.

AMDD 2020 New Year's Celebration and Annual General Meeting

AMDD held a New Year's celebration on January 10 at the Palace Hotel Tokyo. In his greeting, Chairperson Kosuke Kato (President and Director of Edwards Lifesciences Ltd.) looked back on 2019 as the 10th anniversary since AMDD's founding, and ahead to 2020's prospects. Congratulatory speeches were offered by Toshifumi Kojima (Parliamentary Vice-Minister of Health, Labor, and Welfare and Liberal Democratic Party Member of the House of Representatives), Hanako Jimi (Parliamentary Vice-Minister of Health, Labor, and Welfare and Liberal Democratic Party Member of the House of Councillors), Yasuhiro Fujiwara (Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA)), Kazumi Nishikawa (Director, IT Industry Division, Commerce and Information Policy Bureau, Ministry of Economy, Trade, and Industry), and Steve Knode (Deputy Senior Commercial Officer, the U.S. Embassy in Japan). Kenichi Matsumoto (Chairman, Japan Federation of Medical Devices Associations (JFMDA)) then gave the toast, inviting all guests to network and get to know each other's fields.

On March 10, AMDD held its annual general meeting. Proposals for the 2020 and new members of the board of directors were submitted and unanimously approved. At the subsequent special board of directors meeting, Kazuya Ogawa (Chairman and President of Zimmer Biomet G.K.) was appointed as the new chairperson effective that same day, as successor to Chairperson Kosuke Kato who is retiring. See page 1 for a greeting message from the new chairperson.



Mr. T. Kojima Dr. H. Jimi

AMDD 28th Media Lecture

AMDD held its 28th media lecture on January 27 in Tokyo, under the title of "Practicing Shared Decision Making (SDM) in Medical Facilities." Japan SDM pioneer, Dr. Yasuhiro Komatsu (Professor and Chairman at Department of Healthcare Quality and Safety, Gunma University, Graduate School of Medicine) spoke on the importance of SDM, in which medical professionals and patients discuss and jointly decide treatment methods, as well as how it has recently become more prevalent in Japan. With regard to the patient perspective, Ms. Mamiko Matsumura, President of the Kidney Support Association (non-profit organization), and a patient who chose to use insulin pumps for diabetic treatment were invited, and each were asked to share their views on SDM from the patients' perspective respectively. See page 2 for a summary of Dr. Komatsu's lecture.



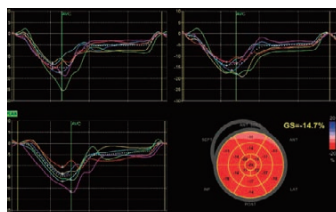
Value of Medical Technology

<Diagnosing and Treating Heart Conditions>

Global Longitudinal Strain (GLS)'s Role in Evaluating Cardiac Functions in Heart Failure and Anti-Cancer Drug Cardiotoxicity in Echocardiography Tests

Echocardiography tests are a useful and safe way to observe and diagnose heart condition in fine detail simply by placing a probe device on the body. Global Longitudinal Strain (GLS) is an echocardiograph that is mainly used to identify ischemic areas, detect areas with delayed contractions, and evaluate dyssynchrony. GLS is an index of the systolic function of the cardiac muscle in the longitudinal direction that was developed in the 2000s and was installed in commercially-sold machines. However, GLS has gained attention in recent years as an index that can complement the Left Ventricular Ejection Fraction (LVEF), which has been the standard index for evaluating cardiac functions. GLS has been listed in the American Society of Echocardiography's expert consensus and the European Society of Cardiology's position papers as a more incisive index. As a method for evaluating cardiac functions for heart failures in which the LVEF is maintained, or as a method for evaluating the cardiotoxicity of anti-cancer drugs, GLS showed more of a tendency to decrease than the decrease in LVEF. There remain issues of differing values between manufacturers echocardiograph tests errors made by those performing the tests. However, human error can be minimized by using machine learning for the automatic analysis function to show an objective index that does not depend on those performing the tests. The graph shows waveforms of multiple cross-sections on one screen, and shows abnormal areas on the bullseye screen (bottom right) so that they are easy to understand.

(Wording: Katsushi Ogihara, GE Healthcare Japan Corporation)



Graph: Waveform analysis of multiple cross-sections on the same screen; abnormal areas shown on the bullseye screen (bottom right).

AMDD's 10th Anniversary Activities —Patient Essays, Volume 3—

To celebrate 2019 marking the 10th anniversary since its founding, AMDD published "I'm Glad I Chose This Treatment! III—Essays by patients who chose advanced treatment," a collection of essays recording the benefits patients received, how their lives were saved, and how the quality of their lives improved thanks to testing and treatments using advanced medical technology.



AMDD published Volume 1 of "I'm Glad I Chose This Treatment!" in 2009 and Volume 2 in 2014 in order to strengthen understanding of the value of advanced medical technology and the contributions that AMDD member companies have made to healthcare in Japan. In the ten years since Volume 1 was published, advanced medical technology such as medical devices and in-vitro diagnostics (IVDs) have become more compact with developments in surgical techniques and the use of technologies such as ICT all evolving significantly. Volume 3 delves into the new technologies and fields not mentioned in Volumes 1 and 2, as well as the progress that has been made over a decade of technological development. Overseen by Dr. Tatsuya Kondo (Chief Executive Officer of Medical Excellence Japan/Chief Executive of the PMDA), the volume covers real patient stories and an interview with Mr. Tsutomu Sekine, a famous Japanese comedian, regarding a heart examination introduced through a TV show that revealed his coronary artery stenosis, as well as the impact on his life before and after surgery.

The essays are also available to download from the AMDD website.

*To receive a copy of the essays, please get in touch via the AMDD website or email AMDD PR representative at: amdd@cosmopr.co.jp



Enabling a Healthier Japan

American Medical Devices and Diagnostics Manufacturers' Association

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