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Awareness of Issues with Single-Use Medical Devices (SUDs) at Clinical Facilities and the Role of Remanufactured SUDs

Background for Single-Use Medical Devices

There are three types of medical devices: single-use medical devices, reusable medical devices, and remanufactured single-use medical devices. As a medical professional, I would like to more widely share the role of single-use medical devices (SUD) and raise awareness of the challenges they must still overcome.

In 2014, the Ministry of Health, Labour, and Welfare (MHLW) issued a notice about the handling single-use medical devices and prohibited their reuse. The notice stated that SUDs must not be reused because hospitals cannot guarantee their safety. In the past, some hospitals washed, sterilized, and then reused reusable medical devices and some SUDs. The notice clarified that such devices cannot be reused without a special, logical reason. The "special reason" must meet various conditions, such as passing inspections by the Infection Control Committee and the Medical Device Safety Control Committee, and gain approval by the Medical Safety Control Committee. It could be interpreted that if the special reason meets the above criteria, devices can be reused. However, meeting these criteria was a high hurdle for individual hospitals, so the notice essentially prohibited reuse.

Introduction of Remanufactured SUDs

In July 2017, the MHLW created a new system for remanufacturing SUDs. The new system allowed for the reuse of SUDs if manufacturers collected their associated medical devices and processed them through dismantling, washing, and sterilization. It became possible to reuse reprocessed SUDs as remanufactured single-use medical devices (R-SUDs).

R-SUDs were authorized and registered as different products than original SUDs, and the remanufacturers and sellers bore all responsibility for safety and collection, etc. In this system, if the remanufacturing process was approved, safety was recognized.

Used medical devices were put into individually sealed containers and were taken to remanufacturers and sellers. However, the rules stated that there must be a person in the remanufacturing process with specialized knowledge about sterilization, such as professional with first class sterilization technician (Certified Sterilization Specialist: CSS) issued by the Japanese Society of Medical Instrumentation. The remanufactured parts were assigned new serial numbers to create traceability and track the number of times an item was remanufactured, and underwent stringent checks before being resold. Hospitals are unable to conduct these measures, so businesses must enter this market gap.

Significance of R-SUDs

What is the significance of creating a new R-SUD system? The system would result in a decrease in cost for the government and hospital management. But doctors and other medical practitioners still feel uncertain about the safety of these items, and may feel there are no advantages. For patients who are adequately covered under health insurance, there is little impact due to the decrease in healthcare costs and do not feel a direct benefit. On the other hand, for remanufacturers this is a new business opportunity.

One characteristic of the R-SUD system is that the advantages and disadvantages are not straightforward as they can differ based on a stakeholder's perspective.

In hospitals, if medical practitioners do not understand the R-SUD business and information is not thoroughly disseminated, things will not go smoothly. So, it will be necessary to have a key person take initiative for the R-SUD business. It takes time to collect used SUDs, so a structure must be introduced for collecting the devices. There are also other challenges with methods for dismantling and washing the devices, and there will be delays with introducing these into the market, so everyone will need to work together.

Dr. Masaki Takashina, M.D., Ph.D.

Graduated from the Osaka University Faculty of Medicine in 1985. Professor, Director of the Sterile Supply, Director of the Supply Center, Director of the Department of Clinical Engineering, and Deputy Director of the Department of Surgery at Osaka University Hospital.

AMDD Enabling a Healthier Japan

10th ANNIVERSARY

AMDD 10th Anniversary Special Lecture 2019: How to Solve Medical Problems through Linkage and Sharing of Data

Necessity for Data Sharing

Against the backdrop of an unprecedented super-aging society, the Japan Agency for Medical Research and Development (AMED) believes their mission for data linkage and sharing is critical.

According to research data on annual population change, in the 1860s, around the time of the Meiji Restoration in Japan, average lifespan was 50 years old. At that time, Japan was a relatively young country with one in five people 50 or older, while the other four were under 50.

However, beginning in the 1970s, the composition of the population shifted dramatically. The percentage of the population that are 50 or older is now projected to increase until the 2040s. Beyond then, the population ratio will again shift and Japan will settle into a 21st century model in which two out of three people are 50 or older.

We have about 20 to 25 years left until the 2040s. For the development of new drugs and medical devices, that is probably only one to two cycles. We will have to speed up our efforts to adapt to this approaching era, or we won't be able to catch up.

Sharing real-world data about patients will be essential, but there will be difficulties. Change will not come from a law or system, but it will be up to each individual. With doctors and clinical laboratory technicians in facilities, universities, academia and the industrial world, each marching to their own drummer, it will not be easy to get everyone in step together.

Two Solutions from AMED

AMED has taken the challenge to address these problems with two solutions.

The first is to accumulate imaging data using Japan Excellence of Diagnostic Imaging (JEDI). AMED will collect and integrate data and use AI to make diagnoses and support treatment.

In order to use AI, it will be necessary to collect a large amount of high-quality data. Since FY2016, six academic societies have been using the Science Information NETwork (SINET5) to accumulate pathological images with annotations.

The Japanese Society of Pathology used the AI engine at the National Institute of Informatics (NII) for pathological diagnoses to create a system that outputs highly probable diagnoses, and a pathologist makes the final judgment. This began in Fukushima Prefecture, and the system is getting results.

The second thing is the Initiative on Rare and Undiagnosed Diseases (IRUD). AMED aims to research and collate the genes of patients nationwide who have rare diseases or undiagnosed diseases, search these results from a database, set a diagnosis, and clarify the patient's condition for treatment.

There are currently about 7,000 rare diseases, and 3,000 to 3,500 of these are related to genetic abnormalities. However, at the global level, rare diseases are more prevalent. For example, for extremely rare developmental impairments with only four reported cases in Japan, there are about 30 cases worldwide.

Many patients with this type of undiagnosed disease are inevitably forced into a never-ending journey of not receiving a diagnosis at their local hospital, not receiving a diagnosis at a regional core hospital, undergoing an inconclusive examination at a university hospital, referral to a national center, and visiting several hospitals only to end up back at the first hospital. If disease information could be collated in a single database, it would be possible to reach a diagnosis immediately. In Europe, there is a rare disease database called Orphanet. But in the future, it will be essential to build a global data sharing system. Linking databases will become more and more important.

How global databases are linked and shared is very important. The feasibility of that is based on building mutual trust, so at first, this will probably start with building trusting relationships.

In Japan, extensive data on healthcare costs and fundamental data on nursing care exists, but if it becomes possible to link them, this will provide important clues into the balance between healthcare and nursing care and the needs of the very elderly for healthcare and for nursing care. In order to do that, it is necessary to make reforms to informed consent that allow the secondary use of acquired data.

We only have 20 years left until the super-aging society will be upon us, so a sense of urgency is needed.

Dr. Makoto Suematsu, M.D., Ph.D.

President, Japan Agency for Medical Research and Development (AMED)

Graduated from Keio University School of Medicine in 1983. Bioengineer Step IV at Institute for Biomedical Engineering, University of California, San Diego. Professor at Department of Biochemistry and Integrative Medical Biology, School of Medicine, Keio University in 2001. Leader, Global Center of Excellence for Life Sciences, Human Metabolomic Systems Biology, Ministry of Education, Culture, Sports, Science, and Technology. Research Director of the Suematsu Gas Biology Project, Japan Science and Technology Agency, Strategic Basic Research Programs (Exploratory Research for Advanced Technologies, or ERATO) in 2009. The Founding President of AMED since 2015. Main research interest: metabolic biochemistry.

Patient's Voice

Achieving a Society Where People with Epilepsy Can Live with Peace of Mind

Ms. Satomi Umemoto
President,
Japan Epilepsy Association (Nami no Kai)

The Association of Parents with Epileptic Children and the Association for the Protection of Epileptic Patients were launched in 1973, which was the start of the movement to improve life for epilepsy patients in Japan. In 1976, the Japan Epilepsy Association (JEA) was established when both of these groups integrated. Currently, the JEA is made up of about 5,000 members, mainly patients with epilepsy and their families, but also support staff such as medical specialists and professionals. As the Japanese branch of the International Bureau for Epilepsy (IBE), the JEA works on many types of topics regarding epilepsy, such as encouraging public awareness, providing support for consultations, conducting research studies, and promoting policies.

Epilepsy is a cranial nerve condition, and it is estimated that there are about a million people in Japan with this disorder. When weak electricity flows into the brain, it "shorts out" the system for some reason and epileptic seizures occur, which are associated with various symptoms. Epilepsy is the general term for a disorder in which these epileptic seizures occur repeatedly.

Diagnoses and treatments for epilepsy have developed rapidly, and it is possible to control about 80% of all the seizure symptoms. The main treatment method is drugs, which are supplemented with surgical procedures and dietary changes. Testing and identification are important for quick and effective treatment. With epilepsy, EEG and imaging diagnoses (MRI, SPECT, PET, MEG) are important. These tests are used to identify the type of epilepsy and the type of epileptic seizure, and treatment starts based on the international classifications for epilepsy and epileptic seizures. In recent years, devices that predict epileptic seizures have been researched and developed, and efforts are being made to help maintain an environment in which epilepsy patients can have peace of mind in their social lives.

In Japan, the government and prefectures have implemented the Program for Maintaining a Regional Structure Linking Diagnosis and Treatment for Epilepsy nationwide. It is now possible to use new anti-epileptic drugs as a result of efforts by many pharmaceutical companies. In addition, we believe that there are strong prospects to further develop devices for testing, identification, and treatment, and that these devices will significantly contribute to achieving a society where people with epilepsy can live with peace of mind.

Japan Epilepsy Association
(Nami no Kai)
https://www.jea-net.jp/

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Physical Therapists

Supporting patients with a
clinical team

Mr. Hideyuki Saito
Vice President,
Japanese Physical Therapy Association (JPTA)

In the Physical Therapists and Occupational Therapists Act (established June 29, 1965), physical therapy is defined as "Having people with physical disabilities engage in therapeutic gymnastics or other exercise, and adding electrical stimulation, massages, heating, or other physical means, mainly in order to restore their basic abilities to move." Physical therapy is promoted in today's regional comprehensive care system by medical insurance, nursing care insurance, and regional care conferences. It is recognized as an occupation that concentrates on supporting self-reliance and has strong potential for preventative nursing care, measures against dementia, and linking healthcare and nursing care. More specifically, it can be said that physical therapy in Japan is coming closer to international standards and the concept of "promotion, prevention, treatment/intervention, habilitation, and rehabilitation" established by the World Confederation for Physical Therapy.

From the perspective of team healthcare and medical devices that support healthcare, in facilities that require medical care in the acute, recovery, and chronic stages, an era is approaching when doctors, nurses, and physical therapists will be core members in team healthcare. In particular, for patients with serious conditions, we can easily imagine that providing physical therapy, which supports self-reliance and increases patients' physical and mental reserve capacity and residual functions, in combination with sophisticated medical devices, which support their lives and health, will protect the dignity of their lives and reduce the burden on doctors and nurses. High-quality medical facilities have teams of healthcare professions that follow an established delegation of authority. It is important to spread this structure throughout Japan.

Finally, regarding the increasing level of sophistication in medical devices that we are already seeing, we cannot avoid developing technical innovations such as robotics, ICT, and artificial intelligence. In closing, I will say that we should work towards creating a paradigm shift from "person-to-person" interactions to "person-to-person-to-medical device" interactions.

Japanese Physical Therapy
Association (JPTA)
http://www.japanpt.or.jp

AMDD Held an Extraordinary General Meeting and 10th Anniversary Event

On September 12, 2019, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held an extraordinary general meeting at the Imperial Hotel, Tokyo, Japan. To open the meeting, Chairman Kosuke Kato (President and Representative Director of Edwards Lifesciences Ltd.) gave a report on AMDD's activities in 2019. The Advocacy Committee then reported on activities over the past 10 years since the group was founded and spoke about future advocacy activities. The general meeting closed with congratulatory speeches from several people who have collaborated with the Japanese medical device industry, including Ms. Arlene Maeda (Senior Commercial Attache, Commercial Department, the U.S. Embassy in Japan) and Mr. Phil Agress (Senior Vice President of the Global Strategy and Analysis Department and General Manager of the Asian Division, Advanced Medical Technology Association (AdvaMed)).

At the AMDD 10th-anniversary event, held at the same time as the general meeting, Dr. Makoto Suematsu (President of the Japan Agency for Medical Research and Development (AMED)) gave a special lecture about AMED's activities for resolving issues in healthcare (for the lecture overview, see page 2).

After the general meeting, AMDD hosted a reception with participants from government agencies and industry groups who have helped promote the medical device industry during the 10 years since AMDD's founding. Several attendees gave congratulatory speeches, including Mr. Masayoshi Shintani (Parliamentary Vice Minister of Health, Labour, and Welfare and Member of the House of Representatives), Mr. Yasuhiro Fujiwara (Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA)), Mr. Steve Knode (Acting Minister-Counselor for Commercial Affairs, the U.S. Embassy in Japan), Mr. Kenichi Matsumoto (Chairman, Japan Federation of Medical Devices Associations (JFMDA)), and Dr. Satoshi Imamura (Vice President, Japan Medical Association (JMA)).

Mr. Shintani Dr. Imamura

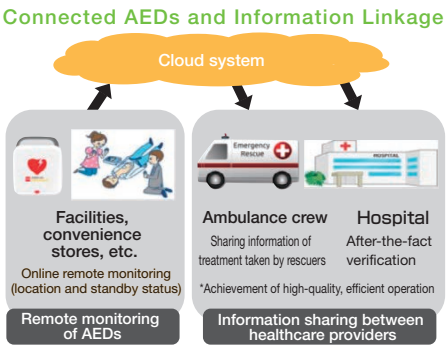
Value of Medical Technology
〈Diagnosing and Treating Heart Conditions〉

Connected AEDs Provide a New Approach for Outside-of-Hospital Cardiac Arrests

According to FY2018 statistics by the Fire and Disaster Management Agency, the number of cardiogenic cardiac arrest cases witnessed outside of hospital facilities rose to 25,538 per year and is anticipated to increase annually. Out of these cases, the number in which AEDs were used by rescuers who happened to be there also increased. Cardiac arrest occurs suddenly without warning and causes convulsions (disordered electrical activity occurs). The heart then loses its function as a pump which sends blood throughout the body, and leads to death within a short time. It is said that early defibrillation using AEDs is the only method that can restore the heart to its normal rhythm.

For sudden cardiac arrest cases, prevention, early awareness, calling the Japanese 119 emergency number, the use of cardiopulmonary resuscitation and AEDs (basic life-support device), transferring the patient to an ambulance crew (advanced life support), restarting the heart, and then proceeding to intensive care without delay all lead to improving the survival rate and rehabilitation rate (chain of survival)*.

In the past, information about life-saving measures was limited to points such as the amount and number of times to administer cardiopulmonary resuscitation (CPR) or electrical shocks. However, if a connected AED is used, detailed data such as the initial EKG and analysis waveforms recorded in the AED can be provided to medical specialists in real time, using a wireless LAN to connect to a dedicated cloud system, before the ambulance crew arrives and before the patient is taken to the hospital. Using a connected AED that connects medical devices to the internet can help prepare the ambulance crew for specific actions that they can take and can help prepare medical practitioners for the early introduction of percutaneous coronary intervention (PCI) and percutaneous cardiopulmonary support (PCPS) after the patient is taken to the hospital. As such, connected AEDs have strong potential to make quicker and more effective contributions to the chain of survival.



*Ministry of Health, Labour, and Welfare: Guidelines for Life-Saving Resuscitation (For Citizens) (2015)
(Responsibility for wording: Yusuke Fujimoto, Stryker Japan KK)

AMDD's 10th Anniversary Activities

Dream Medical Devices and IVD Idea Contest

Elementary school children nationwide submitted about 150 applications to the "You Can Be an Inventor! Dream Machines and Tests to Check and Treat Patients Idea Contest" (held as an event related to the 2019 Japan-US Medtech and Healthtech Innovation Forum Kobe). Out of these applications, ten children were chosen to make final presentations at the judging and award ceremony on November 9 at the Konan University Port Island Campus in Hyogo Prefecture. Even though they were nervous, the children confidently presented their ideas in front of the judges and the audience. More than 500 people visited the venue and enjoyed the hands-on medical device booths and poster exhibits of all the contest entries.

10th Anniversary Booklet

AMDD issued a 10th anniversary booklet called "AMDD: 10-Year History and Beyond" that summarized the history of AMDD over the past 10 years since its founding in 2009 and AMDD's thoughts for the future. This publication presented information such as proposals for maintaining and revising the various laws and regulations towards resolving device lag. AMDD has had a major impact in overcoming device lag from when the organization was an ACCJ Medical Device and IVD Subcommittee to its work today. Included are also articles about the experiences of expert advisors of the Central Social Insurance Medical Council, trends in the insurance reimbursement system, and the future of Japan healthcare.

*To obtain the anniversary booklet, please contact the email address below.
AMDD PR Office: amdd@cosmopr.co.jp

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American Medical Devices and Diagnostics Manufacturers' Association

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