

# AMDD Vol.29

## NEWSLETTER

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### **2018 AMDD General Meeting Special Lecture: The Future of Japanese Healthcare and Expectations for Medical Devices**

#### [The Current State of Japanese Healthcare and the Stance of the Japan Medical Association](#)

Although Japanese healthcare is highly regarded internationally, just how long this situation is sustainable is frequently a topic of discussion. The amount of healthcare expenditure per capita increases rapidly from around age 70. In this context, the government is attempting to control social security expenditure to ensure fiscal soundness, drawing up its Honebuto Policy each year. The Japan Medical Association (JMA) determines whether this policy is fair and unbiased from two perspectives, whether it consists of measures that contribute to the safety of healthcare and whether the measures enable the maintenance of universal healthcare.

If social security is generous, it will be a financial burden, but if the state of social security is reconsidered and enhanced, the anxiety of the public will be resolved. JMA would like to expand this kind of a positive cycle.

#### [Extending Healthy Lifespan and Supporting the Development of Medical Devices](#)

The biggest issue presented by an aging society is the fact that the labor force is reduced. Healthcare expenditure is supported by the working generation, but if aging continues to advance, the working generation will be unable to support it. To this end, we must increase the number of the healthy elderly and extend healthy lifespan to ensure that people are able to remain active throughout their lifetime. If healthy lifespan is extended, employment will also be extended and tax revenue will increase, leading to more social security funds used for healthcare expenditure and long-term care costs.

One of the initiatives of the JMA is the centralization of data from physical checkups conducted at various locations such as schools, workplaces, and municipalities as a

lifetime health project in accordance with the life stages of the Japanese public.

The other is the promotion of “2020 Declarations for Achieving Health-Conscious Communities and Workplaces” created in collaboration with the Nippon Kenko Kaigi. There are eight declarations, each with their respective numerical targets. Of these, JMA places importance on Declaration 2 “To increase the number of municipalities preventing lifestyle-related diseases from becoming severe in collaboration with family physicians of 800 towns and municipalities.” JMA actively addressed this issue by creating a training system to enhance the family physician function. In 2018, the number of towns and municipalities involved already exceeded 1000.

There are also tasks related to supporting the development and commercialization of medical devices led by physicians. JMA supports the realization of exceptional ideas by physicians. JMA requests and registers ideas, judge projects, acts as a bridge to AMED, provides consultations on patent filings, and connects consultants as well as holding backup seminars.

#### Overview of the Strategic Innovation Promotion Program (SIP)

SIP (Strategic Innovation Promotion Program) is a national program created to realize innovation in science and technology in Japan. It is led by the Council for Science, Technology and Innovation, one of the advisory bodies of the Cabinet Office. It is positioned as a function that promotes initiatives that cover everything from basic research to practical realization and commercialization beyond the framework of government ministries. SIP does not merely offer research support but it also has the ability to allocate its own budget and implement programs in society.

One term for SIP is five years, and in its second term, a “healthcare” budget was created for the first time. This budget will be used to research advanced programs for establishing “advanced diagnostic and treatment systems by AI hospitals.” This is the first attempt of its kind, but there are high hopes for the research results and eventual implementation.



#### **Dr. Satoshi Imamura**

Dr. Imamura is Vice-President of the Japan Medical Association, Committee Member of the Central Social Insurance Medical Council, and Director of Imamura Clinic. He graduated from the Akita University School of Medicine in 1977, and worked at the Mitsui Memorial Hospital, Kanagawa Children’s Medical Center, and Shizuoka General Hospital. After serving as a lecturer at Hamamatsu University School of Medicine in 1989, he opened Imamura Clinic in 1991.

## Special Discussion - Ask the Experts: The Ideal Vision for Health Technology Assessment (HTA)

Developing efficient and effective healthcare systems that generate innovation and lead to a sustainable healthcare insurance system is a universal issue. To achieve these aims, Japan is considering introducing a Health Technology Assessment (HTA).

A trial introduction of cost effectiveness evaluations was conducted in fiscal 2016, and the country is beginning work towards full-scale introduction.

HTA was actively discussed at the International Society for Health Economics and Outcomes Research (ISPOR)\* held in Japan among four participants, Professor Michael Drummond of the Centre for Health Economics, The University of York, Associate Professor Rosanna Tarricone of the Department of Social and Political Science at Bocconi University and Associate Dean of the Government, Health, and Not for Profit Division at the SDA Bocconi School of Management, as well as Director Makoto Tamura of the AMDD Medical Technology Policy Institute, and Chairman Kosuke Kato.

### Assessment for Introducing HTA in Japan

**Kato:** As we work towards introducing HTA in Japan, today we hope to hear your frank opinions on this topic.

**Drummond:** The first thing that concerned me was that Japan is attempting to introduce HTA while maintaining its existing drug pricing system. These two have areas where they are incompatible. When you think about the impact HTA would have in the current pricing system, it would be useful to consider evidence collected during the period after the price was first set.

Companies should be motivated to collect more data. If they can specify the clinical and economic value of a medical device in the three-year period from the time a price was set until its revision, this would be a major advantage and generate sufficient motivation for companies.

**Tamura:** The details have still not been finalized in Japan, and as you mention, the government has not changed the current drug pricing system over to HTA. France introduced the HTA system while maintaining its former reimbursement methods. Do you think it is possible for it to function successfully as it is in France?

**Drummond:** From a long-term perspective, based on the premise of introducing HTA, it would not make sense to set prices using the current method. From the government's perspective, HTA appears to be a pricing system that functions well, but it is still in the experimental stage.



(From left) Dr. Drummond, Dr. Tarricone, Mr. Kato, Dr. Tamura

Another thing I would like to mention is that countries who introduced HTA face an even more difficult problem of how the government should make policy decisions based on the results.

Australia was the first country to implement this, and I wrote a paper about it. The paper was titled the “the thin end of the boomerang” in the sense that there was the possibility of it coming back to hit the very person who started the process. What I wanted to say was that from the perspective of the industry, this is seen as an experiment. It should be seen as an opportunity for confirming how to use various kinds of data acquired such as sufficient information on the efficacy and safety of medical devices, and coming to an understanding with physicians, who are the users, to generate superior evidence that will help both companies and patients.

**Tarricone:** I am in complete agreement with Dr. Drummond. I think that the Japanese government is basically using HTA as a means to control prices. Originally, HTA was meant to control costs, but it has recently come to be recognized as an effective way of rewarding technologies and, more in general, healthcare programs that bring values and not spending resources on programs that are unnecessary.

There is a strong tendency for countries attempting to introduce HTA to use it as a means to protect their own position and as an excuse to control costs.

If that is also the case in Japan, then as Dr. Drummond says, in addition to the advantage of generating superior evidence, the industry should try to give more power to patients. The position of patients in Japan is weak, and corporations should support to help them be more assertive.

**Drummond:** One thing that could be done by studying the HTAs of various countries is to gain a better understanding of the level of involvement by stakeholders and the level of transparency for policy decisions. At this ISPOR conference, there was a session focusing on patient participation in Asian countries. In the U.K., there are patient representatives on each committee of the National Institute for Health and Care Excellence, and there are opportunities for them to speak out on various occasions. It is just getting started in Japan, but I am optimistic about patient participation.



(From left) Dr. Drummond, Dr. Tarricone, Mr. Kato, Dr. Tamura

## About Pricing

**Tamura:** In Japan, HTA will most likely be introduced in the area of pricing based on value. With the current trial introduction, there is the possibility that reimbursement prices may be raised. In fact, the reimbursement price was raised for a certain medical device.

**Drummond:** Pricing should change according to how much value the technology is determined to have, but in fact, although prices can be lowered, it is difficult to raise prices. The U.K. government says that prices are flexible with HTA, but this tends to be a one-way flexibility; downwards.

**Kato:** In the U.K. too?

**Drummond:** Yes. That is to say, there are many examples of prices based on HTA, and although there are cases where it is higher than the price desired by the government, in many cases the price goes down or is maintained at the same level. However, the issues faced by medical devices in the European countries are not with the policies of the central government, but at the procurement stage of the healthcare system. Generally speaking, people try to pounce on the cheapest price without considering the performance of the device. I think that for device manufacturers, this is much more troublesome than the issues that occur with the central government.

**Tarricone:** I think that in the future, this will be a difficult issue for corporations. If we move in the direction of truly assessing value, competition will become even more severe. This is because in order to demonstrate added value compared to the standard treatment, that product would include high research and development costs compared to the past or present situation. Most likely, the cost of producing new medical devices with true added value will be high, but the concept of value that the government is referring to is one-way as Dr. Drummond said.

## Issues Faced by HTA

**Tamura:** In Japan, the scope of cost-effectiveness assessments has not yet been decided. Currently, in a trial, existing products are the main target for HTA. One thing I wanted to ask is that the U.K. was conducting Multiple Technology Assessments (MTA) that targeted existing products, but currently it is focusing on Single Technology Assessments (STA) targeting mainly new products. Why is the U.K. not focusing on existing products?

**Drummond:** Existing treatments may indicate not the product but the type of treatment. Like a person with a heart disorder who is hospitalized frequently. There may not be an existing product to compare with the new device being introduced, but the patient is currently incurring costs. What I am talking about are the costs of current standard treatments, and even if there is no product, the cost of treatment is not zero.

**Kato:** In Japan last summer, there was a major discussion regarding what should be done about the threshold for the incremental cost-effectiveness ratio (ICER). Ultimately, no one was able to decide upon a price or method. It ended up being tentatively set at 5 million yen, or around 30,000 pounds, but what are your thoughts on this?

**Drummond:** The U.K. does stipulate a threshold, but actually most countries in Europe have not set a threshold. Countries that do have a fixed threshold all make it constantly flexible. Even if there is a technology you want to support, there may be those who assert the need for improvement if it exceeds the threshold even with the slightest margin.



However, if there isn't a threshold and 12 HTAs are conducted, the cost per quality-adjusted life year (QALY) of the 12 types of treatment measures would be compared. Even if there is no threshold, we need to think about value in keeping with the price. If we can eliminate the threshold, we still cannot eliminate the need to consider value in keeping with the price.

**Tamura:** It is dependent on how you can obtain agreement from many people.

**Drummond:** In the beginning in the U.K., NICE was saying that it would not set a threshold. Then, there was someone who researched the decisions made for the first 50 technologies NICE assessed. As a result, it revealed that technologies under 20,000 pounds per QALY had an extremely high possibility of positive recommendations, while those of approximately 30,000 pounds per QALY had an extremely low probability of positive recommendations. NICE decided to set a given scope of 20,000 to 30,000 pounds per QALY, and my colleague also researched this. As a result, an even lower threshold was suggested. When introducing a new technology, you must eliminate something in order to make funds available to spend elsewhere, and these results are based on what would be lost by doing so. NICE was of the opinion that it was too low and would not accept it. Meanwhile, those making the payments say that a low threshold was better. In other words, if the industry can show sufficiently high-quality evidence that a product has superior cost effectiveness, this should be the main point.

**Kato:** Is there anything that we can do right now?

**Drummond:** The issue for industry organizations is the scale of corporations in the medical device area. While there are large corporations with abundant resources to generate evidence, there are also small corporations where this is difficult. For this reason, the important thing for industry organizations is to ensure that both small and large corporations can profit simultaneously. This is an extremely difficult issue.

I co-wrote a paper on the theme of how to motivate medical device companies who conduct this type of research. Currently, in most cases, large corporations first develop the product and conduct the research, and all of the corporations that enter the market after them end up saying that their product is the same as the large corporation's product. Our claim is not that large corporations should pay for all research costs, but that if a device is registered, research expenses should be paid in accordance with the number of patients who would use the registered device. By doing so, small corporations would be able to contribute to research without having to make payments as high as those of the large corporations who have sold many devices. We thought this was a good idea, but unfortunately, no one is doing this yet.

**Tarricone:** I think that industry has a social responsibility to collaborate with universities to utilize and enhance the overall knowledge level of physicians and patients. Doing so would lead to an understanding of the correct concept of HTA not as a means of controlling costs, but as a means of allocating budget where it is worthiest.

**Kato:** Thank you for today. We hope that you will continue to give us advice and share your insights regarding the introduction of HTA in Japan in order to make it into a better system.

\*Now known as ISPOR — The Professional Society for Health Economics and Outcomes Research.

**Brief Bios:**



**Dr. Michael Drummond**

Professor, Centre for Health Economics, The University of York.  
Specializes in the economic assessment of treatments and programs in the healthcare field, conducting economic assessments in a wide range of areas including the elderly, neonatal intensive care, and vaccination programs. Honorary doctorates from City University (London), Erasmus University (Rotterdam), and the University of Lisbon.



**Dr. Rosanna Tarricone**

Associate Professor of the Department of Social and Political Science at Bocconi University and Associate Dean of the Government, Health, and Not for Profit Division at the SDA Bocconi School of Management. Main research areas include healthcare management, economic analysis of health services, healthcare policy, and Health Technology Assessment. Serves as an advisor to public agencies and private organizations in Italy and overseas.



**Mr. Kosuke Kato**

Chairman, American Medical Devices and Diagnostics Manufacturers' Association (AMDD).  
Managing Director, Edwards Lifesciences Limited



**Dr. Makoto Tamura**

Representative Director, Healthcare System Planning Institute, Specially Appointed Professor, International University of Health and Welfare Graduate School. Director of the AMDD Medical Technology Policy Institute from 2017 and Senior Research Fellow at the Japan Association for the Advancement of Medical Equipment Medical Device Strategy Institute.

## AMDD Held Diversity Forum ~Further Promoting Diversity in the Medical Device Industry~

On September 21, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held its "AMDD Diversity Forum" in Tokyo as the culmination of its diversity activities undertaken as a medical device industry organization.

AMDD launched a project team to promote diversity within the medical device industry in 2016. The first theme member companies selected was "diversity of sales divisions" and since then two "AMDD Sales Woman Network" events were conducted.

At the AMDD Diversity Forum, two saleswomen who participated in the Sales Woman Network, Dr. Emiko Kono of the Department of Digestive Surgery, Takatsuki Red Cross Hospital, who supports active participation of female physicians at the Association for Empowerment of Women Gastrointestinal Surgeons (AEGIS-Women), and Yuko Uenishi of the Gender Equality Bureau of the Cabinet Office participated in a panel discussion. Approximately 70 people attended the Forum including HR and PR personnel from AMDD member companies and male members of management from the industry. The panelists discussed issues faced from the perspective of saleswomen and female physicians and shared hints for ways to resolve these issues.

In the panel discussion, rewarding aspects of working in sales for medical devices were discussed along with team systems and possibilities for work sharing. According to Dr. Kono, who has promoted work sharing from a physician's perspective, "women in sales and female physicians have the same concerns", she added, "making work sharing into a team system would make it easier for both men and women. Disclosing and sharing everything about your situation and strengthening ties is the secret to sustaining work relationships."

The discussion was followed by an active Q&A session. In response to a question from a male member of management, "What kind of superior would you find easy to talk to?" a woman in sales responded, "If your superior first discloses something, it is easier to open up. I think it is important that disclosure is not just one way, but mutual."

Bringing the event to a successful close, Tatsuo Achiwa, Director of AMDD (President & Representative Director of Nippon Becton Dickinson Company, Ltd.) stressed that AMDD would continue to not only support women in sales going forward but would undertake diversity and inclusion from a variety of perspectives such as balancing long-term care and illness.





## Value of Medical Technology <Diagnosis and Treatment of Heart Disease> Devices for the Treatment of Heart Disease that Alleviate Stress on the Body and Support High Quality Healthcare

Maintaining normal heart function is crucial for maintaining one's health. In the therapeutic area of heart disease, many advanced medical technologies have been introduced in Japan that alleviate stress on the body.

For example, coronary disease (mainly angina / myocardial infarction), which is most common among heart diseases, leads to a lack of oxygen supply to the heart muscle due to the accumulation of plaque (fatty deposits) on the coronary artery that supplies blood to the heart, narrowing or blocking the artery and leading to chest pain and increasing the risk of heart attacks. Until the early 1970's, coronary artery bypass graft surgery where the body is cut wide open was the main treatment method. But now, minimally invasive percutaneous coronary intervention (PCI) is widely used, where a catheter is inserted from the groin or the wrist to treat the blocked blood vessels. This treatment alleviates the physical stress on patients during treatment. PCI and other advanced technologies, such as thin catheters for complex lesions and stents coated with drugs to lower the rate of incidence of restenosis, have advanced dramatically to reduce repeated treatments for patients and improve early recovery after surgery. Other technologies have also been developed to reduce the adherence of blood clots to the treatment area after a procedure.



In another example, the first minimally invasive catheter treatment device was approved in Japan in 2017 and introduced as a new treatment in April 2018 for mitral valve regurgitation (MR), a type of valvular heart disease. Going forward, this method is expected to contribute towards enhancing QOL for many MR patients.



(Text: Isoda, Abbott Vascular Japan Co., Ltd.)

## AMDD Held Extraordinary General Meeting

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held an extraordinary general meeting on September 13. Chairman Kosuke Kato (Edwards Lifesciences Limited) reflected on the year's activities in his opening remarks and touched upon the fact that next year will mark the 10th anniversary of AMDD. He asked member companies for their continued cooperation. In the keynote speech, Arlene Mayeda from the U.S. Embassy mentioned that a number of issues related to medical devices are being addressed in Japan-U.S. economic talks and introduced Senior Commercial Officer Steve Knode as a new member, confirming that the U.S. Embassy and AMDD will continue to work together.



Dr. Satoshi Imamura, Vice-President of the Japan Medical Association, gave a special lecture entitled "The Future of Japanese Healthcare and Expectations of Medical Devices". (See page 1 for an abstract of Dr. Imamura's lecture.)