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JAPAN MEDICAL ASSOCIATION

JMAJ

Policy Address[*1]

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Yoshitake YOKOKURA[1]

First, I would like to discuss the FY2016 revision of the medical fee schedule that we have been strongly advocating to the government sectors involved. With the help of the members of the Japan Medical Association (JMA), we continuously raised awareness on the serious financial hardship that many medical institutions face and the economic benefits of increasing the wages for healthcare professionals, who account for more than 3 million people in the Japanese population. Although we were unable to transfer the total amount of the national health insurance drug price reduction to the medical fee because of the postponed consumption tax increase, a ceiling on budgetary request, and other very difficult financial situations, as a result of our efforts, the medical fee schedule generally increased by 0.49%, and the physicians' medical fee schedule increased by 0.56%.

The media is currently reporting that the implementation of the increase in consumption tax from 8% to 10%, which was already postponed until April 2017, may be postponed again. Medical and long-term care professionals strongly support increasing the consumption tax rate and utilizing the increased revenue to fund the medical and long-term care sectors. Even if the consumption tax increase is deferred again, we strongly advocate that the government secure funding to ensure social security services for all generations in Japan and to prepare for the upcoming 2025 challenge by establishing the Community-based Comprehensive Care System to cover services ranging from child-rearing to geriatric care.

Furthermore, healthy financial management of medical institutions is a prerequisite for providing people with trustful high-quality care. If the government is going to endanger the financial management of medical institutions by increasing the consumption tax for medical services, then they have their priorities wrong. The government has announced that it will reach a decision on the consumption tax exemption by the end of the FY2017 tax system revision. All medical societies involved will present a unified front to work toward the resolution of this issue.

As you are aware, the G7 Summit will be held in Ise Shima in May, this year (2016), to be followed by the G7 Health Ministers Meeting in Kobe in September. Prime Minister Shinzo Abe has already announced that he will promote public health crisis management and universal health coverage to actively and continuously strengthen healthcare systems.

The healthcare system of Japan is renowned for contributing to the world's highest life expectancy. During my policy address at the 131st JMA House of Delegates Extraordinary Session in March 2014, I spoke about Japan becoming a world model by reforming the upcoming super-aged society that no nation has ever experienced into "a society of assurance" through reformation and rebirth, taking into consideration the national economy and population dynamics. I also stated that I would like JMA to contribute to bringing happiness to the people of the world by sharing information about our excellent

1 President, Japan Medical Association, Tokyo, Japan (jmaintl@po.med.or.jp).

healthcare system.

My wish remains unchanged, and I will strive to make the Japanese healthcare system a true global model in bringing assurance to the world by building communities in which *kakaritsuke* physicians*2 play a major role, developing human resources to deal with the upcoming reforms, and establishing an organization strong enough to continue guiding the healthcare policies of the government.

Now, allow me to elaborate on building a community in which *kakaritsuke* physicians play a major role. Thus far, Japan's goal was to improve the accessibility of health care across the nation through our universal health insurance system so that any citizen could receive high-quality care, regardless of when they needed care and who and where they were. We now face a birth rate that continues to decrease, an increasingly aging population, and continued concentration of the population in metropolitan areas. The important thing is how medical institutions can collaborate and how different functions can be allocated among institutions to continue enjoying what we have achieved and to ensure high-quality care for local communities. I am certain that *kakaritsuke* physicians, who are rooted in communities, will play a key role in resolving these issues.

Prefectures across the nation are currently working on developing their own community medicine plans. To ensure that community medicine planning will not be used to reduce the number of hospital beds or control healthcare expenditures but to ensure that each community can continue to provide the care that local residents require with no surplus or shortage, it is important that local authorities promote *kakaritsuke* physician-oriented community planning and accurately understand the local situation. Furthermore, the needs for recovery care and chronic care are expected to increase in the future. Therefore, it is essential to build a network to provide people with medical and long-term care, preventive medicine, and welfare programs in which *kakaritsuke* physicians play a key role, as the community-based comprehensive care system will be central to the healthcare

provision.

The significance of local medical associations is paramount in any such stage. JMA expects local medical associations to fulfill their duties as major players, and we will continue to support the local medical associations as the national level.

Another important consideration for dealing with the super-aged population in Japan is to strive for a society in which people enjoy longer healthy life, older people can continue to work with a sense of fulfillment, and all citizens can remain active at work and/or in society. This requires more effort focused on extending healthy life, such as improving lifestyles and daily habits, guided by *kakaritsuke* physicians, and systematizing life-long health projects through the centralized system to manage healthcare information. These thoughts prompted me to design a training program from JMA that is available to prefectural medical associations. Starting from April 2016, this program will evaluate the ideal framework for *kakaritsuke* physicians' services that can be trusted by local residents and help maintain and improve these services.

The healthcare expenditure is expected to proportionally increase in response to the extension of healthy lifespan and progression toward an aging population. As a proactive attempt to optimize healthcare expenditure through preventive medicine and health management, I would like to extend JMA's work by collaborating with economic organizations, insurers, and local governments through the Japan Health Conference, which was established in July 2015, with the help of JMA members across the nation.

Next, I would like to discuss human resource development from the perspective of providing guidance to those who can lead the reform. It was local physicians who first worked in public health. Without the devotion and years of effort by our respectable eminent predecessors, the society that we enjoy today, with a healthy and long lifespan, would not exist. This is something we should never forget.

Those in charge need to be bold and innovative in their efforts to further plan a method of

*2 A physician who people can consult on any issues, is well versed in the up-to-date medical information, can refer a patient to a specialist or specialized medical institution when needed, and is a trustworthy and familiar figure with comprehensive capabilities entrusted with community medicine, health, and welfare.

community development that is capable of responding to the changes in the environment that influence medical practice. Developing human resources capable of such a task requires a serious and united effort by the medical community.

Medical graduates from a medical school that is not appropriately accredited will not be qualified to receive clinical training in the United States after 2023. The Japan Accreditation Council for Medical Education was established in December 2015 to address this so-called 2023 accreditation requirement by evaluating medical education by specialty. JMA and the Association of Japanese Medical Colleges (AJMC) launched a joint committee and compiled suggestions for training and allocating physicians in different specialties.

New findings accumulate day after day in medical science and practice and the knowledge and skills that physicians are expected to possess continue to broaden and become increasingly advanced. Physicians are expected to continuously acquire new knowledge and skills and accordingly, we need to explore an ideal approach to develop proper human resources that meet their current and future demands. Therefore, JMA will further enrich our Continuing Medical Education Program and continue to debate the ideal framework for educating physicians, in cooperation with AJMC and hospital organizations as well as the Japanese Association of Medical Sciences.

The new specialist system, in particular, will require more in-depth consideration from now on.

This system was originally intended to revise the various current specialist systems that are less unorganized, in the hope of serving public trust better by revising the systems based on physicians' professional autonomy. The role of the Japanese Medical Specialty Board is to standardize the assessments for specialists solely from academic and scientific perspectives. However, the current trajectory has the risk of increasing the geographical bias in physicians' distribution and becoming an obstacle to the comprehensive community health care system.

A special review board will be established under the Social Security Council Medical Group to review this topic further in the future. The key is to not disrupt community medicine by making

sudden revisions to the system because patients and the general public are the ones who will ultimately suffer from this disruption. To prevent such a situation from occurring, JMA will continue to proactively work so that the design of the new specialist system will be compatible with community medicine and secure the transparency of the Japanese Medical Specialty Board's governance.

It is also crucial to build a strong organization that can continue to lead healthcare policy making. More than 3 million people are employed in the medical and healthcare sectors. I believe that the responsibility for ensuring their employment and active workplaces and maintaining the healthcare system, which was founded on "trust and collaboration," should fall upon JMA because it is the one and only professional organization for physicians at the national level.

Medical care is one of the key elements in social infrastructure, and physicians in charge not only come face-to-face with the most precious human lives through medical science and practice, treating disease and easing patients' suffering, but also contribute to the protection of the health for all the people and promotion of overall social welfare.

JMA was organized to fulfill these roles and has served the local communities and society with good will and faith. One of the most significant achievements of JMA is the establishment of the universal health insurance system in 1961, when Japan was at the beginning of the high-speed economic growth era, as part of infrastructure in daily activities based on the spirit of mutual aid, which we have firmly adhered to since its establishment.

On the other hand, Japan's social security system has undergone repeated patchwork revisions. As we face the time for reform, with medical and long-term care being the main focus of the changes, it is essential to make structural reforms that look toward the future and envision beyond the Year 2025, when Japan's post-war baby boomers reach the age of 75. When making these reforms, the risk of compromising the original purpose of the social security system by emphasizing only on the financial aspect should also be considered. In other words, communities and society must be rebuilt before economic restructuring, and the burden and benefit should be shared among the people in a way that they

find agreeable. Thus, the public will develop a foundation of trust in the government and its social security services. I am confident that we will succeed in establishing a sustainable social security system when various stakeholders involved in medicine can deepen their collaborations based on this trust.

The pressure to restrict the range of benefit of public health insurance will probably continue in the name of regulation reform or a growth strategy aimed at curtailing government expenditures. However, the priority of healthcare policy management should be to contribute to a stable society by promoting social security services; it should not be based on the government's finances. Therefore, we medical profession need to continuously propose methods to the government by which we can provide appropriate health care with no excess or shortage as we proceed with the reforms that meet the needs of the time.

Perseverance is required. No reform can be achieved in a day. JMA must uphold its Code of Principles and continue to take steps toward establishing a sustainable social security system, collaborating with as many physicians and other people as possible. Through these steps, we shall also work to increase our influence on the society by further strengthening our organization with the help of prefectural and municipal medical associations. In addition, JMA will take the lead to create the ideal framework for community medicine collaborations in the IT era, including by promoting utilization of the Medical Doctor Qualification Certificate. Moreover, we will utilize the data gained from such collaborations, and continue to propose evidence-based healthcare policies to the general public and government that are founded on an understanding of current local situations and scrutiny of existing policies.

JMA will strive to make the healthcare system of Japan a model that truly leads the world to a society of assurance by making efforts to build communities in which *kakaritsuke* physicians play a major role, developing human resources to deal with the impending reforms, and establishing an organization strong enough to continue guiding the healthcare policies.

The late Eitaka Tsuboi, the former JMA president who passed away in February of this year, said that, "If JMA is to propose a reform to a society, physicians and medical associations must have a sense of mission and return to the origin of medicine, which is to be responsible for this nation and its people." His words will always be in my heart as I continue to work to contribute to people's happiness, focusing on the world from a local viewpoint.

Lastly, I would like to mention that this March marks the 5th year since the Great East Japan Earthquake that brought unprecedented damage to Japan. Once again, I express my condolences to all the people who lost their lives in the disaster.

Together with the Disaster Victims' Health Support Liaison Council, JMA will continue to assist with the reconstruction of affected communities through building a system of collaboration with mid- to long-term medical support in mind.

As I resume my post for another term, my heart goes out to those communities affected by the disaster, and I renew my desire to continue supporting this nation with the power of medicine. I will continue to manage JMA's affairs with your help. Thank you very much.

The Challenges of Japanese Community Medicine from the Global Health Perspective[*1]

Global Health Committee of the Japan Medical Association[1]

Introduction

In 2008, when the Toyako G8 Summit took place, the Japan Medical Association (JMA) initiated the Global Health Committee. Since then, activities continued with 2 years as one term. For 2014 and 2015, the 4th Global Health Committee took place.

During the 3rd term, Dr. Yoshitake Yokokura, the JMA President, focused on the topic of "International contribution through the activity of World Medical Association (WMA) and community medicine in Japan." As a result, JMA played a major role in WMA activities, such as the revision of Declaration of Helsinki. In addition, JMA Junior Doctors Network (JMA-JDN) was established during this time.

On the other hand, a concern was raised whether this involvement of the international activities could contribute to improve community medicine in Japan. For example, how the finding from the Declaration of Helsinki would link with the improvement of community medicine, and how the current contents discussed at the World Health Organization (WHO) would improve the Japanese community medicine. Based on these discussions, the 4th term investigation topic was set as "the challenges of Japanese community medicine from the global health perspective."

In Japan, discussion about global health problems is not new. For example, the Ebola virus disease in 2015 was a hot topic in Japan. While there was much support for West Africa, Japan took various measures to minimize possible public health risks. In 2016, the Zika virus was the most talked about matter. However, it is important to note that it is not all infectious diseases that are imported from the developing countries. The United Nations Millennium Development Goals was ended in 2015, and the new initiatives have already been started towards the Sustainable Development Goals in 2016. In the new era of sustainable development, when Japan faces and may continue to face financial difficulties, Japan might utilize better and sustainable health measures used by the countries with limited resources. In order for this to occur, it is important to re-evaluate the value of "local" while paying attention to "global" and make use of lessons learned from "local" successful actions.

For the medical community in Japan, "local" is almost equivalent to the communities in the villages, towns and cities. In Japan where aging and population reduction are taking place, JMA has been aiming at strengthening health care with "adherence to universal coverage by the public health insurance" and "contribution to public health safety policy" as key concepts.

In the recent years, consumption taxes have increased from 5% to 8%. The increased amount of the taxes is supposed to be used for the resources of social security in Japan, and the Medical Care Act and Long-term Care Insurance Act have been revised. In each medical district of each prefecture, it was mandated to create a community health care initiative, and it was required that it should ensure "a system that provides efficient and effective healthcare for the local residents." The creation of the "Community-based Comprehensive Care system" has been advocated for this reason as well. Now is the time for transforming the healthcare system in Japan. Not a hospital care first. "One

should be able to live where they are used to living for their whole life," by selecting a "Kakaritsuke physician.*²" There should be a "system that provides efficient and effective healthcare for the local residents": and it is desired and created in the community.

Then, what does it mean by the "system that provides efficient and effective healthcare for the local residents"? For medical beneficiaries (patients), it might mean for a clinic that is available late night, holidays, and open 24 hours. However, if these were the terms, the doctors will be obliged to overwork. A rotation system may improve the situation slightly. Although the burden on them varies depending on the number of patients during the month, it will become physically impossible when medical doctors get older to work with this system. At this point, teaming up with a doctor from a hospital for assistance is not an option. When a public installation is carried out as the responsibility of a social security, should doctor behave as a public service provider or as a private citizen? When such a system urges doctors to play a role as public service providers, appropriate public support is necessary and citizens should raise awareness about it.

How should the "Community-based Comprehensive Care system" be created? In order to do this, the health care and long-term care needs of each individual must be collected at a community level. There must be a person responsible for a program; he or she tracks for what reason, at what time support is needed, and determines who needs which support by whom. When the Community-based Comprehensive Care system is created, a chief executive to run the whole operation needs to be assigned, something that is not considered at the current status. It is difficult for community medicine to function as an organisation unless we think about the whole community as one facility for all the medical and nursing care.

Although the roles of the 'local' have been emphasized in Japan, its roles tend to be overlooked in global health. Under the name of global health, developed countries with much wealth and power have focused on building a scale-up of the invested programs and evidence building which they can compare globally. They are spreading the belief in "numbers." They made people believe that numbers are important. To complement the weakness of this current trend, the concept of "Slow Research" was born derived from the Slow Food movement. This is a concept proposed by a medical anthropologist in the US. In this concept, "local" is not just a place, but taken as a means. It is advocating that we should not solely learn from "global," but also from 'local actions' as a means of health care activity, thereby transferring various pieces of knowledge and wisdom obtained from 'a local action' to 'other local actions.'

The expression "viewed from global health" found in the current report topic is possible to interpret as "viewed from health care activities in various local communities in developing countries."

This document first reports what Japanese community medicine can learn from various health care measures taken in developing countries. These are Ebola virus disease measures, maternal child health handbook, Indonesia local initiatives, environment-improving health activities in developing countries, and the positive deviance approach which pays more attention to successful solutions than problem identification. Next, it reports the activities of the WMA, CMAAO, Takemi Program, and JMA-JDN activities.

Lastly, the future global health activities by the JMA are recommended.

From Global Communities to Japanese Communities

Lessons learned from the outbreak of Ebola Virus Disease

The beginning
A 2-year-old boy who lived in Gueckedou in Guinea died on December 6th, 2013. His mother, older sister, and grandmother followed him. However, no one suspected that their deaths were caused by the Ebola virus.

As of March of 2014, Ebola virus infection has been found among local residents as well as

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*² A kakaritsuke physician is a physician who people can consult on any issues, is well versed in the up-to-date medical information, can refer a patient to a specialist or specialized medical institution when needed, and is a trustworthy and familiar figure with comprehensive capabilities entrusted with community medicine, health, and welfare.
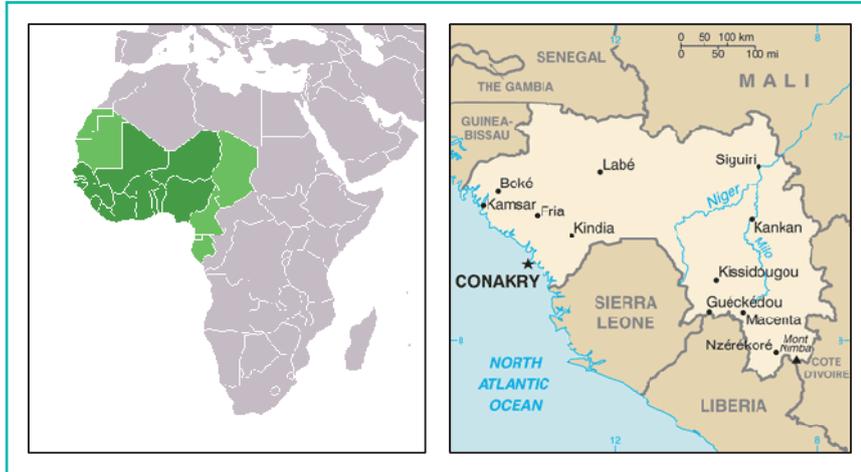
Fig. 1   West Africa (World atlas modified by Yamamoto)

medical service providers, and a few dozens of people died of Ebola virus disease (EVD). Although EVD was uncommon in West Africa, people still believed that the outbreak would be contained soon. However… it spread.

Timeline of the outbreak

2014

Jun 17th

Seven people living in the capital of Liberia died of EVD.

Jun 23rd

Doctors Without Borders (Médecins Sans Frontières; MSF) announced that the situation was out of control.

Jul 27th

Liberia closed its border in order to prevent the virus from spreading.

Jul 31st

Sierra Leone declared a state of emergency.

Aug 6th

Liberia declared a state of emergency.

Aug 8th

The WHO declared a Public Health Emergency of International Concern.

Aug 13th

Guinea declared a state of emergency.

Aug 15th

MSF announced that EVD was spreading faster beyond their control.

Aug 29th

The first EVD patient in Senegal was confirmed positive.

Sep 18th
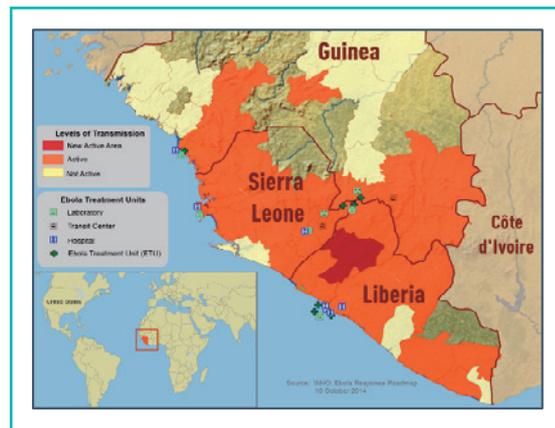
Fig. 2   Ebola response roadmap (WHO, 2014)

The UN Security Council held an emergency meeting and adopted a resolution on public health.

Why did the Ebola virus spread?

There were several reasons. First, Gueckedou, the place where outbreak occurred first, is located in the southern part of Guinea, near border with Liberia and Sierra Leone. Second, the population in that area expanded from 79,140 in 1996 to 221,715 in 2008 because of civil war in Liberia and Sierra Leone, resulting in an influx of refugees. Rapid urbanization, civil war, and other factors caused shortage in local health resources and precipitated people's distrust for health systems.

There were also other reasons unique to the

areas affected. In these areas, there was a kind of tradition that people expressed their condolences by caressing the dead, which paved the way to an Ebola outbreak. In addition, delay in the early response made the situation worse.

The difficulties of risk assessment

At an early stage of an outbreak, risk assessment is not an easy task. Risk assessment is measured by the equation below:

$$Risk = Severity\ of\ symptom \times Probability\ of\ infection$$

However, it is often impossible to have a precise count of infected people at the early stage of an outbreak. Local population dynamics change as infection spreads, pathogens may undergo mutation, and epidemiological tools are continuously changing. Therefore, the risk assessment methodology is not yet fully established. Furthermore, an overall picture of an outbreak changes over time. In spite of these facts, we need to respond to outbreaks at a very early stage. Repeated evaluations and feedback are essential for a well-timed necessary response.

What is the Ebola virus?

The natural host of the Ebola virus is the fruit bat. The virus transmits from bats or other primates to humans. This virus was first found in Sudan (present: South Sudan) in June of 1976. A watchman suddenly developed a high fever of 39 degrees Celsius with headache and abdominal pain and received treatment. He later died of severe bleeding from the nose and intestine. Next to him, 2 others developed symptoms. Infection spread through blood or medical equipment. The number of people who were infected and died were 284 and 151, respectively. Later on, in West Africa, more than 10 Ebola outbreaks occurred. However, the outbreak in 2014 was different in the magnitude from previous outbreaks. Although it is a Public Health Emergency of International Concern, Japan's contribution was limited. A bitter regret!

The way forward

Upon this situation, the Government of Japan made an important decision on the development of human resources related to international infectious disease emergency. The Early Response and Emergency Relief Team was to be established in the Japan Medical Team for Disaster Relief. It is composed of 500 rosters.

Lessons learned from Ebola Virus Disease Preparedness: Part 2

Ebola virus disease

Ebola, previously known as Ebola hemorrhagic fever, is an acute viral hemorrhagic disease caused by infection with *Ebolavirus* and characterized by its high fatality rate. There is no standard treatment for this disease, and supportive care is considered as the best intervention. The disease is now referred to as EVD because patients do not necessarily exhibit hemorrhage as a symptom.

The past outbreaks of EVD

EVD was initially identified in 1976 in two simultaneous outbreaks, one in Nzara and the other in Yambuku in Sudan. Yambuku is a village near the Ebola River, from which the disease takes its name. EVD outbreaks have occurred intermittently in tropical regions of sub-Saharan Africa. The WHO reports that between 1976 and 2013 there were 24 outbreaks involving 1,716 cases in tatal. Most outbreaks were of brief duration, and were contained before spreading beyond limited regions. However, the outbreak in 2014-2015 was quite different from those in the past; it spread to the United States and Europe. The death toll was 28,639 as of February 2016, making it the largest outbreak in the history of EVD.

The EVD of 2014-2015 expanded from a small village in Guinea to Liberia, Sierra Leone, Nigeria, Senegal, and Mari. Foreign health care workers who were involved in the EVD response were also infected. Moreover, new cases occurred through secondary infection in the United States, Spain, and the United Kingdom. On August 8, 2014, as EVD continued to spread, the WHO declared the outbreak a public health emergency. In May 2015, the WHO finally declared that the outbreak was over.

Favipiravir (AVIGAN®), a new antiviral medication

Favipiravir, or AVIGAN®, is a new antiviral medication developed by Fuji Film Company and Toyama Chemical that is effective against viral infectious diseases such as avian influenza and EVD. It is a pyrazinecarboxamide derivative and works by interrupting the transcription of many RNA viruses. In animal experiments, favipiravir was shown to be effective against influenza viruses, West Nile virus, yellow fever virus, and foot-and-mouth disease virus, as well

as other flaviviruses including arena viruses, bunya viruses, and alpha viruses. Favipiravir does not inhibit the RNA activity involved in DNA synthesis in mammalian cells, and is therefore not toxic to the host. In addition, favipiravir has shown effectiveness against the Ebola virus in several laboratory studies. Fravipiravir might be useful in treating EVD even in pandemics, although no solid clinical trial has been performed yet.

On March 26, 2014, the Japanese Ministry of Health, Labor and Welfare (MHLW) conditionally approved favipiravir by considering the potential emergence of anti-viral medication-resistant influenza. The conditions however, were very strict. First, there needed to be more evidence of clinical effectiveness in humans. Second, because of the teratogenicity and embryotoxicity demonstrated in animal testing, favipiravir was to be produced and administered to patients only after a decision by the MHLW to use favipiravir during an outbreak of anti-viral medication-resistant influenza. This meant that, without the government's permission, favipiravir could not be manufactured or stocked in Japan. Such strict requirements posed a great challenge for Fuji Film Company and Toyama Chemical. Several international agencies have shown strong interest in the possibility of developing favipiravir, but both companies hoped to contribute to the patient welfare in Japan.

Involvement of the JMA

Being placed in a difficult position, Fuji Film Company and Toyama Chemical consulted the JMA. The JMA confirmed the effectiveness of favipiravir and that this medication could be one of the final solutions for an outbreak of anti-viral medication-resistant influenza or EVD. Also, favipiravir had the potential to save patients' lives around the world and contribute to global heath.

Doctors have medical discretion in clinical decision-making. After considering several factors including scientific evidence, the advantages and disadvantages of possible treatments, and the patient relationship, doctors select the best treatment option for each patient. The strict restrictions on favipiravir production can compromise doctors' medical discretion. The JMA hoped to overcome this difficulty.

Favipiravir and EVD

EVD is listed in the Act on Prevention of Infectious Diseases and Medical Care for Patients with Infections in Japan, which came into effect in 1999, and is categorized as a Category 1 infectious disease (Category 1 Disease) along with other viral hemorrhagic fevers, plague, and smallpox. Therefore, EVD patients should be treated at one of the designated and specified infectious disease hospitals (Specified Hospitals) and Class 1 Infectious Disease Hospitals (Class 1 Hospitals). However, high-risk patients with fever and a travel history to/from West Africa might go to ordinary clinics or community hospitals for initial consultation. The JMA recognized this potential and collaborated with the public health department.

Additionally, because of possible teratogenicity and embryotoxicity, special attention should be paid when treating women, especially pregnant women. It is not socially or ethically easy to administer a medication with a known side effect to a patient, even when the patient's condition is critical. On the other hand, the loss of both a pregnant woman and her fetus because of a delay in treatment should be prevented. In medical education and in practice, how to prioritize the life of a mother and that of a fetus is an ethical issue for doctors in the clinical setting. There is no one definitive answer, but saving mothers is often considered as the first priority.

In October 2015, the WMA adopted the Resolution on Ebola Viral Disease, which supports the use of medication not authorized by governments when the Paragraph 37 of the WMA Declaration of Helsinki is followed. Paragraph 37 states:

Unproven Interventions in Clinical Practice 37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available. *<WMA Declaration of Helsinki (revised in 2013), Paragraph 37>*

As of October 21, 2014, no drug is proven effective against EVD. Since this represents an international crisis, using a new medication such as favipiravir against EVD would be acceptable if Paragraph 37 of the Declaration of Helsinki (rev. 2013) is respected along with other WMA resolutions that include EVD.

Use of favipiravir by France

With the support of the Japanese government, Fuji Film Company and Toyama Chemical provided favipiravir to France, which was treating EVD patients in Guinea. The clinical study, named the JIKI study (JIKI means "hope" in the local language), was led by Dr. Denis Malvy of l'Institut national de la santé et de la recherche médicale (Inserm). Usually, a clinical trial is conducted as a double-blind randomized study to reduce bias; however, it was considered unethical to use a placebo in such a critical situation. Dr. Malvy also decided against a randomized controlled trial and instead designed a study where all participants would receive the same high-dose favipiravir treatment. In low-income countries like Guinea and Liberia, it is not easy for patients in remote areas to visit clinics in towns, both geographically and financially. Dr. Malvy and his colleagues pursued a difficult treatment plan in a high-risk environment and later published a paper to demonstrate the effectiveness of favipiravir against EVD. The study results indicated that patients with lower virus loads and no multiple organ dysfunction had a lower mortality rate, and that treatment delays led to poor outcomes.

Lessons from the 2014-2015 EVD outbreak

In the EVD outbreak of 2014-2015, Japan contributed to a global health emergency by using favipiravir. A drug invented by Japanese pharmaceutical companies saved lives in distant parts of the world. This was a breakthrough for Japan. The next step would be healthcare workers from Japan working locally to treat patients. Research and development efforts should also continue. Another EVD outbreak can occur in the future, and there are other infectious diseases globally with no solid treatment options. The lessons learned from the 2014-2015 EVD outbreak will give us great leverage in future disease control.

Lessons learned without borders: Reverse-imported Maternal and Child Health (MCH) Handbook after its evolution in developing countries

The origin of the Maternal and Child Health (MCH) Handbook is Japan

The MCH Handbook is a home-based record book that contains essential information kept by the family, to promote and maintain the health of mothers and children. In 1948, the first version of the MCH Handbook was distributed by the Ministry of Health and Welfare, Japan. The MCH Handbook consists of records of pregnancy, delivery, and child development and health information on mothers and child-rearing. Now, obstetricians, pediatricians, public health nurses, and midwives write down medical records in the MCH Handbooks. Parents bring in their MCH Handbooks to clinics when their children get sick. The coverage is almost 100% in Japan.

Japan's infant mortality rate (IMR) has shown a drastic decrease from 76 per 1,000 live births in 1947 to 2.1 in 2014. This is one of the lowest IMRs in the world. The life expectancy at birth as of 2014 was 86.8 years for women and 80.5 for men.

A joint Japanese and American research team investigated the reasons why the IMR in Japan was so low. The team concluded that there were five possible explanations for Japan's low IMR, one of which was the use of the MCH Handbook. Japan's experience is different from that of many countries. However, it is certain that the MCH Handbook program is just as important in ensuring the quality of life of mothers and children.

MCH Handbook around the world

Now, an MCH Handbook program is being introduced in more than 30 countries including African countries. An MCH Handbook program based on the needs of mothers and children is the most effective when many health professionals and health care workers are actively involved in one's care and when a sufficient health care delivery system exists. The contents of the handbook should be appropriate for the community. When there are many non-literate parents, many pictures and figures should be added. The basic concept of the MCH Handbook is very similar in many countries. However, the content, colors, pictures, and illustrations in the various handbooks are quite diverse, because each country
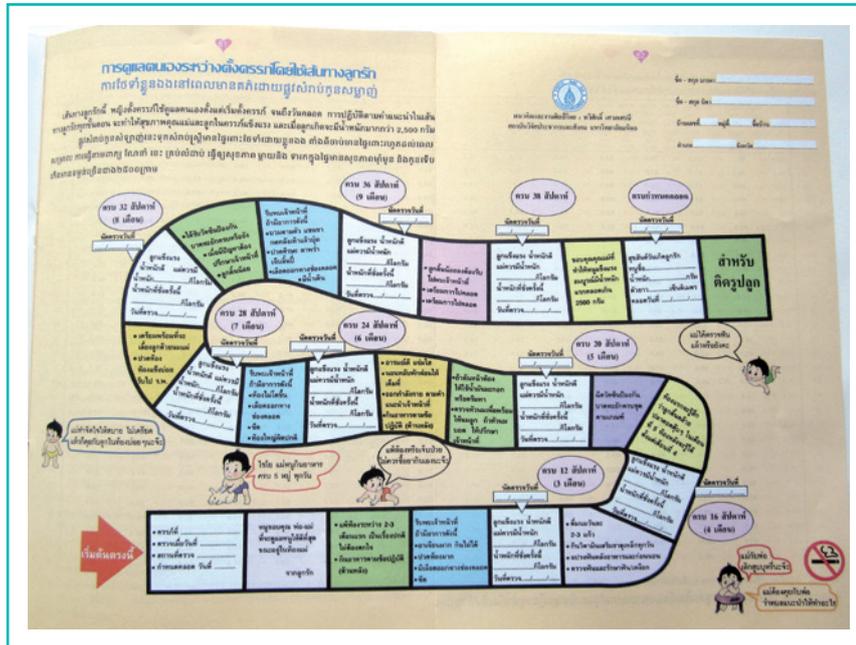
Fig. 3   The MCH Handbook in Thailand is very attractive with many illustrations.

has its own unique cultures and customs.

The 9th International Conference on MCH Handbook was held by the Ministry of Public Health of the Republic of Cameroon and the International Committee on the MCH Handbook on September of 2015 in Yaoundé, Cameroon. Over 250 participants from 20 countries gathered under the theme "Effective Use of the MCH Handbook: A Tool to Continue Progress for MDGs 4 and 5 beyond 2015." The official opening of the conference was attended by 8 ministers, including the Cameroonian Minister of Public Health and the Minister of Women's Affairs.

The conference was conducted in English and French, official languages of Cameroon, securing equal participation of both English- and French-speaking countries. Many health professionals in African countries stated that the MCH Handbook is a miracle tool to ensure the continuum of care for maternal, newborn, and child health.

What Japan can learn from the experience of developing countries

In developing countries, many health records and educational materials have been published, such as pregnancy examination records, child growth charts, immunization cards, and many beautiful posters and pamphlets for the health education of mothers and children. When their MCH Handbooks were first developed, these existing materials and records were utilized in their MCH Handbooks. The keyword is "*user-friendly*" for the MCH Handbooks with many descriptive pictures and illustrations and fewer explanatory sentences. The idea of a user-friendly MCH Handbook should also be imported to Japan, because young mothers in Japan prefer pictures and illustrations over written documents.

The 10th International Conference on the MCH Handbook will be held in Tokyo from November 23 to 25, 2016. The theme for the conference is "Leave No One Behind." It will enhance the use of the MCH Handbook in the delivery of MCH services to disadvantaged groups, including the poor, the disabled, migrants, refugees, and other minority groups.

I hope the conference will give an opportunity to share the lessons learned regarding the MCH Handbook beyond the borders between Japan and many other countries.

Local initiatives based on trust

There is little to learn from less disaster-prepared countries.

Being one of the most disaster-prepared countries in the world, there is little for Japan to learn from less prepared countries. Why? The greatest reason is that many of those less-prepared countries were colonies until 60 or 70 years ago, and their suzerain states were never serious about taking measures against natural disaster to protect colonial residents. For example, the director of the Association of Medical Doctors of ASIA (AMDA) Indonesia Branch sarcastically describes his nation as being a department store of disasters; He is the first Muslim person who became a physician after Indonesia became independent because the Netherlands had never allowed a non-Christian to become a physician.

Lessons from local initiatives

The AMDA Indonesia Branch director is a descendant of the sultan of the South Sulawesi Island. A sultan is a Muslim political leader. As mentioned ealier, there is little that Japan can learn from a country that is less prepared against disaster; however, Dr. Shigeru Suganami, President of AMDA, personally learned a great deal from him. Above all of these lessons, "local initiative" comes at the top of the list—meaning that we should respect the initiatives of those who are familiar with local situations. Local initiatives are based on trust from local people. A local initiative cannot exist without people's trust. In an extreme expression, "If you are mistakenly sent to hell, I will go to hell with you; if you are to go to heaven, I will go to heaven, too."

On December 26, 2004, a mega-earthquake hit the cost of the Sumatra Island followed by a giant tsunami. This disaster resulted in an enormous number of disaster victims with nearly 230 thousand deaths. The Indonesian government issued an order prohibiting medical teams from abroad from entering the regions where the Aceh independence movement was active.

Then, as unbelievable as it may be, the director of the AMDA Indonesia Branch said, "The sultan of the South Sulawesi Island married the sultan of the Aceh about 100 years ago, and the people in the Aceh independence movement will welcome us as their family." Surprisingly, he was right, and AMDA medical teams were welcomed. The areas of the Aceh independence movement had also suffered extensive damage. Naturally,

our medical teams started making a round of visits. We asked local people what they wanted to help with their reconstruction. They requested a meeting place. Their mosque, which served as their spiritual anchor, had collapsed due to the disaster. The building was reconstructed as an AMDA community center.

Similar experiences in Japan

On March 11, 2011, the Great East Japan Earthquake occurred. Dr. Suganami went through a similar experience. Professor Taro Yamamoto of the Nagasaki University Institute of Tropical Medicine and Dr. Suganami entered Kamaishi City and Otsuchi Town, which were damaged by the disaster. Neither of them had ever been to these areas. A female physician who was originally from Kamaishi City and a nurse from Otsuchi Town were with them, serving as both local navigators and assistants as we all stayed in a shelter and provided medical care. Without their support, medical teams from both AMDA and Nagasaki University would have been unable to work so promptly. Their motivation for joining the AMDA medical teams was pure and simple; they were hoping to go back home and learn about the whereabouts of their families by joining the AMDA's medical relief activities.

Disaster management proposal for the Nankai Trough earthquake and tsunami

In order to prepare against the Nankai Trough earthquake and tsunami that are bound to occur in the near future, AMDA is in the process of establishing a disaster management platform based on the agreement with the Governors of Kochi and Tokushima. More than 40 physicians originally from Tokushima Prefecture are registered in Kawasaki Medical School, Okayama. The key players of the AMDA Nankai Trough Disaster Management Platform in Tokushima Prefecture will be the Kawasaki Medical School graduates. We asked Mr. Seiji Kawasaki, Chief Director of Kawasaki Medical School, to send physicians who are from Tokushima Prefecture. Because Kawasaki Medical School also has many physicians who are from Kochi Prefecture, Chief Director Kawasaki decided to involve Kochi Prefecture as well, and a 4-party agreement, among Kawasaki Medical School, AMDA, Kochi Prefecture, and Tokushima Prefecture, was swiftly realized.

The following is a proposal. Medical schools and institutions across Japan have many medical

staff who have some kinds of bonds with the regions that will be affected by the Nankai Trough earthquake and tsunami. Why not establish a dispatch program with a priority to send these people to their hometowns? The dispatched medical staff will have the joy of being able to contribute to the local people of their hometown and their families. The local people will have a pleasure of being cared for by familiar physicians and nurses in their time of despair. Local medical institutions and governments will take comfort in having support available from outside the affected areas. Without joy, nothing can be done appropriately.

So who will bear the cost of dispatching medical staff? Of course, the national government. One month will suffice as a period of compensation. Without compensation, those who manage medical institutions with strong Hippocratic spirit will have to suffer. The most important thing is having local exchanges among governments, medical associations, and medical institutions before a Nankai Trough disaster strikes. This is especially true for local governments because *regulations at normal times become the greatest obstacle in times of emergency*. This is the secret of secrets of local initiatives in Japan because Japan is a leading constitutional state in the world and because Japan is a bureaucratic nation with the least level of corruption in the world. The cornerstone of the AMDA Nankai Trough Disaster Management Platform lies in the extensive collaboration of local governments across 4 prefectures.

The essential element of local initiatives in Japan will be the local medical associations. Dr. Suganami has served as the president of the Otsu Medical Association of Okayama Prefecture for 2 years (plus 4 years as the vice-president), so he understands it very well. It is hoped that this concept of local initiatives that was learned in disaster medicine relief in Asia will be useful in the upcoming Nankai Trough earthquake and tsunami.

Lessons from the world: To overcome new public health crises

Current health issues in Japan
Japan is sometimes referred to as having a good example of universal health coverage among developing countries as it was the country that achieved universal health insurance coverage in the early post-war period when Japan was not rich enough to achieve it. However, the current Japanese healthcare system also has many issues to overcome. Specifically, a rapid increase in aged and impoverished populations challenges the sustainability of the Japanese health and welfare systems. An increase in nuclear families and live-alone households has weakened the informal local safety net stemming from community solidarity. Consequently, new social issues such as "the unattended death" or "lonely death" and the expansion of health disparities have emerged.

These social trends may explain the unsatisfactory achievement of the Health Japan 21 (*Kenko Nippon 21*), the government-initiated nationwide health promotion movement since 2001. Less than 20% of all goals have been achieved, because the individuals who have strong chronic social stresses are less likely to start and continue healthy activities with their own reflective intents. Upon reflecting on the poor achievement of the movement, the new stage of the movement, called the Health Japan 21 the Second Term, set "the reduction of health disparity" as one of its primary and ultimate targets in addition to the expansion of healthy life longevity. To achieve these targets, its primary strategy focuses not only on individuals but also on the social environment.

The population strategy targeting social environment is strongly recommended by the 2008 Final Report of the WHO's Commission on Social Determinants of Health headed by Sir Michael Marmot, the current president of the WMA. However, effective experiences and know-how are not sufficient in Japan, and no remarkable achievements have been observed so far.

Successful cases from developing countries
There are many impoverished people in low- and middle-income countries, and it is unrealistic to expect that many of those people will give priority to having better health over more attractive choices. This means that what Japan needs—good examples of health promotion and life-benefiting activities—in fact exists in those countries. Although health problems may be different among countries, there should be great opportunities for lessons for Japan from developing countries.

Here are some examples. Financial management is difficult for many socially vulnerable

people. Simply providing cash may not be effective as some may use the cash for gambling, drinking, and so on. There is a good solution for this in Mexico: conditional cash transfer. Under the system, cash is provided for impoverished people under a series of conditions. Those conditions include making their children attend school, buying necessary nutritious foods. Conditional cash transfer could be applied for Japan.

Microcredit is another good strategy of social welfare. This Nobel-awarded, group-based non-collateral small-amount loan system has had tremendous success all over the world and could be applied in Japan, too. Microcredit is especially important as it could lead to the strengthening of community solidarity and social capital, which is a key target of Health Japan 21 the Second Term.

The positive deviance approach is another applicable scheme, which has attracted many global health communities as a promising approach to health promotion in the context of limited resources. In this approach, people find the successful cases despite the difficult contexts, analyze them, and apply them for all remaining people. Good examples include a nutritional program in famine incidences and malaria prevention. In Japan, a positive deviance approach could be used for the cases that suffer from serious resource shortages, e.g., long-term care prevention in some depopulated areas and sanitation management in disaster evacuation sites.

The Hope Soap Project in South Africa is a new and unique health promotion idea. An NGO has long committed to preventing gastrointestinal infections among children in this region; however, some children have less access to health education opportunities. For such children, the NGO started to provide soaps with small toys inside. To get those toys out, children start washing their hands heavily using the toy-in soaps, resulting in the 70% reduction in gastrointestinal infections. Because of the toys, children can unconsciously change their health behavior and get clean hands, not because they care for their own health but simply because they want to have a toy. This concept of behavioral modification by "being healthy unconsciously" could be a great lesson for Japan, where the number of people who ignore their own health is increasing.

Lessons from developing countries: application
The important thing we should capture from these excellent examples is that these activities could only be achieved with close collaborations of multiple sectors and players, including education, employment, and financing. This cross-disciplinary collaboration evokes Japan's current concept of "Community-based Comprehensive Care" in which close collaborations between governmental and private service agencies are required. Physicians, long-term-care service providers, community-building consultants, and many other organizations should participate in a new healthcare scheme. All of the examples mentioned above are great examples of such cross-disciplinary collaborations. Many healthcare activities in Japan are often vertically segmented with little cross-disciplinary interaction. We should learn more from these examples of other countries worldwide.

Some proposals for the Japan Medical Association
These important lessons from all over the world present some suggestions for the future activities of the JMA. First, the JMA should increase the opportunities for its members and clinicians to learn more about global health and local public health activities. This should work to increase collaboration between JMA members, clinicians, and community public health practitioners more effectively. The opportunities to mutually learn regional/local good practices among communities will be also effective. Those activities should also have an international environment. For example, it would benefit both Japan and other countries to mutually learn about good regional/local examples from each other under collaboration with the WMA. The attitude of "mutual leaning" is essential in conquering Japan's current health crises and contributing to the world.

Positive deviance approach

Within many of the communities and organizations, there are individuals and groups who take different but positive actions. These individuals face the same problems as the rest of the people, but solve the problems in better ways. These individuals are called "Positive Deviant," and the action is called "Positive Deviance." Here, such actions and people will be collectively referred to as PosDev.

In the 1990s, there was an attempt to increase

the PosDev during the undernutrition crisis in Vietnam. 'Save the Children USA' and Vietnam National Institute of Nutrition were the first to conduct such a measure. First, the nutritional surveys were conducted in four villages. Of three hundred 3-year-old children and below, 64% were suffering from undernutrition, mainly in low body weight. Usually, experts of nutrition and health look at these numbers. Then, they would first investigate the 64% of the children in detail to figure out the root cause and come up with solutions. However, since time and budget were limited, instead of directly tackling with the solution, the practitioners in charge of the matter decided to focus on the remaining 36% of children that were not suffering from undernutrition. Setting aside the children of the village leaders and influential members, they examined the reason of their PosDev who were in a good nutrition condition, despite them being poor like the rest of the population.

As a result, three features in PosDev were identified. First, the parents of the PosDev brought back small crabs and shrimps from the field for their children to eat. All of them were free. Second, each time the children would touch something dirty, the parent would wash the children's hands regardless of how many times it takes. The third feature was that these children would eat four to five meals a day, with the help of other family members while the parents were out to work, whereas, children in a typical family would only have two meals a day.

The next step was to make these PosDev actions a routine so a two-week workshop was conducted. The targets were now the mothers of the children who fell in the 64% (ones who have undernutrition children). The families were instructed to practice the three aforementioned PosDev features, and the weights of the children were measured at the end of the two weeks. They were asked to continue to take these actions even after returning home. As a result, two years later, 85% of the children suffering from undernutrition improved their health. This PosDev approach was then implemented on 250 villages, and the health of 50,000 children were improved after seven years.

This approach was later spread to 55 countries across the world. It has also been used for nosocomial infection control of MRSA infection in the United States, infant mortality improve-

ment in Pakistan, obesity measures in various countries, and nutritional measures for pregnant women.

PosDev approach is effective as a means particularly to overcome behavioral changes, especially nutritional problems and health problems. It is the most effective in bringing changes to chronic issues and habits. In addition, this approach focuses on the assets (advantages) than the needs (disadvantages, shortcomings). Experts tend to focus on the weakness of the target area and have strong wills to solve the problem. However, by focusing on the assets, it is possible for the demand side and the supply side to be active in healthcare services in a sustainable manner.

In Japan, similar actions are already on-going without using the name of PosDev. For example, when investigating suicide, experts tend to look at the areas in which suicide is prevalent and examine the reasons for these behaviors. However, Ms. Mayumi Oka from Wakayama Prefectural Medical University has investigated the lowest suicide rate region, Kaifu-cho, Tokushima Prefecture, over 4 years. She examined the reasons why this area pertained low suicide rates. Although it is difficult to say how to define features for the PosDev, she came to figure out a number of characteristics from interviews with local residents.

1. In Kaifu-cho, there is little red feather fundraising. The elderly participant rate is low for senior clubs. They value the participation of different types of people.
2. They emphasize "problem solving skills," when nominating town leaders. They do not require educational background, but it is a people-oriented principle.
3. There are not many people who think that people like themselves cannot influence the government decisions. They do not belittle themselves.
4. When feeling ill or worried, people take action towards early consultation, thinking that someone would help them. There are many people who answered that they do not feel embarrassment when they ask for help or advice when they are worried. In Kaifu-cho, such a way of thinking is referred to as "submit disease to city."
5. Not many residents answered that they have everyday cooperative relationships with their

neighbors. However, many replied that they do have casual run-ins with their neighbors or greet their neighbors regularly. They value on relatively loose bond among themselves.

These features are not ones that can be apparent after a two-week research, such as the PosDev study in Vietnam. Investigating local advantages, that is, suicide from a less prevalent area, rather than comparing with a prevalent area, is very similar to the PosDev approach. This approach has a lot of potential to be applicable effectively in local societies in the Japanese aging and population-declining society.

Activity Reports of the WMA and CMAAO

The activities of the WMA and the Confederation of Medical Associations in Asia and Oceania (CMAAO) during the 4th period of the Global Health Committee revolved around international contribution in healthcare through introducing various healthcare challenges that the JMA has been working for. The list below is a summary.

1. Improved the WMA's presence by the success of the WMA Tokyo Council Sessions
2. Made suggestions for the Trans-Atlantic Trade and Investment Partnership (TTIP) negotiations, referencing to our request to uphold Japan's universal health insurance system in the TPP framework and our accomplishment from the negotiations with the government
3. Successful zoonosis management under "One Health" by the World Veterinary Association (WVA) and WMA
4. Collaborated with the WHO Western Pacific Regional Office (WPRO) in CMAAO activities
5. Responded to the request for aid from the Myanmar government
6. Dispatched a medical assistance team for the colored powder accident in Taiwan
7. Disaster relief (e.g., mega-earthquake in Nepal)

As illustrated in this list, introducing our experiences in Japan to overseas areas and responding to requests for aid from other nations were steadily carried out. The following describes the details of some representative activities.

WMA activities

In April of 2014, the WMA Tokyo Council Session was held with about 250 people from 40 countries; the Prime Minister Abe; the then Minister Tamura of Health, Labour and Welfare; and the Vice Governor Ando of Tokyo Metropolitan Government were present as the guests of honor at the opening. The Japan Medical Association Junior Doctors Network (JMA-JDN) also held their JDN meeting concurrently. The 3-day meeting was successfully completed, and Dr. Kloiber, the WMA's Secretary General, expressed high appreciation. The WMA's presence was greatly improved through the collaboration and strong influence of the national government, public administration, municipal governments, and JMA; we could say that the meeting was held in the ideal manner for the WMA.

In October of the same year, the WMA Durban General Assembly was held in the Republic of South Africa. This meeting was held in Africa while the Ebola virus fever was still on the rampage after it had spread from West African countries such as Guinea, Liberia, and Sierra Leone. There was a sense of urgency in the meetings as the Doctors Without Borders (Médicins San Frontières) had just released a report concerning their medical activities in the infected regions. The General Assembly adopted the WMA Resolution on Ebola Viral Disease, which recommends prompt provision of personal protective equipment and sufficient training to reduce the risk of cross-infection, as well as the WMA Resolution on Unproven Therapy and the Ebola Virus, which urges physicians to conform to the Declaration of Helsinki Article 37 when treating the Ebola virus disease.

In November of 2014, a commemorative ceremony was held in Helsinki, Finland, to mark the 50th anniversary of the WMA Declaration of Helsinki. The WMA Declaration of Helsinki is the most important guidelines that stipulate the ethical principles in medical research involving humans as study subjects, including those studies that use test agents and data that are identifiable as the human-origin. Since its adoption in June of 1964 at the WMA Helsinki General Assembly, it has undergone several amendments as medicine advances and healthcare changes. The latest version was adopted in October of 2013 at the Fortaleza General Assembly in Brazil. Also, in November, the WMA held the H20 International Health Summit in Melbourne, Australia, as the G20

Summit was concurrently held.

In April of 2015, the WMA Oslo Council Session was held in Norway. In deliberation, the WMA Proposed Statement on Trade Agreements and Public Health, which urges countries to secure stable healthcare provisions under the TPP and TTIP, was adopted as the Council Resolution.

In May of the same year, the Global Conference on One Health Concept co-hosted by the WVA and WMA was held in Madrid, Spain. In October of 2012, the WVA and WMA had signed a memorandum of understanding with the aim of mutual cooperation of veterinarians and physicians under the concept of One Health in order to promote the concept. In response, the JMA and Japan Veterinary Medical Association signed an agreement concerning the promotion of academic collaboration in November of 2013, and medical and veterinary associations in 31 municipalities subsequently have signed similar agreements.

In October of 2015, the WMA Moscow General Assembly was held in Russia, and Sir Michael Marmot (UK) was inaugurated as a new WMA president. The General Assembly adopted 3 emergency resolutions including the health problem of the Syrian refugees. Dr. Yoshitake Yokokura, the JMA President, explained the JMA's efforts to the Japanese government regarding its TPP negotiations and stated that the JMA was successful in having the government include a statement that assures the universal health insurance in the Overview of TPP Agreement released by the Cabinet Secretariat. He urged the WMA to make necessary recommendations to protect people's health and closely observe to avoid letting the Investor-State Dispute Settlement procedures and ratchet clauses damage the healthcare systems of different nations. In the public debate session, Dr. Yokokura also invited the audience to aid the revitalization project for the Tree of Hippocrates, which is dying on the Kos Island in Greece. He also talked to the Kazakhstan Medical Association about cooperation on radiation medicine.

CMAAO activities

In September of 2014, the CMAAO Manila General Assembly was held in the Philippines. During the stay, the JMA visited Dr. Takeshi Kasai, WPRO Director of Program Management, and they exchanged opinions and discussed regional information on infectious diseases, Ebola hemorrhagic fever, and dengue fever. Dr. Jose Asa Sabili, a former president of the Philippines Medical Association, was inaugurated as the new president. The council decided to establish a fund for disaster relief for the member national medical associations. The symposium was held with a theme of "Health Database in an Information Society." The Indian Medical Association reported serious problems of multi-drug resistant bacteria and a re-emerging outbreak of tuberculosis in developing countries, and a WHO staff member from the WPRO Stop Tuberculosis Unit and Leprosy Elimination Team was invited to describe the current status of the diseases and management options. At the end of the general assembly, the CMAAO Resolution on Ethical Frameworks for Health Databases and Human Genetic Databases was adopted.

In September of 2015, the CMAAO Myanmar General Assembly was held in Yangon. The symposium was also held at the same venue with the theme "Ensuring Food Safety: An Important Challenge Today." Professor Rai Mra, the president of the Myanmar Medical Association, was inaugurated as a new CMAAO president. In the discussion of the proposed resolution on food safety, Dr. Yokokura stated that securing safe water should take priority over food safety; the council unanimously agreed to incorporate this statement in the preamble, and the CMAAO Resolution on Ensuring Food Safety was adopted. In addition, the JMA came forward to host the 32nd CMAAO General Assembly in 2017 and was approved by the council.

Request for aid from the Myanmar government

Dr. Thein Thein Htay, the Myanmar Deputy Minister of Health, asked Dr. Yokokura for the JMA's assistance in the future of Myanmar healthcare, and a meeting was held during the CMAAO sessions. Deputy Minister requested assistance in 2 areas: one concerning making efforts and preparing for disaster medicine and the other concerning the introduction of a universal health insurance system.

Myanmar has been attempting to promote disaster medicine preparedness as the collabo-

rated efforts of the Ministry of Health (MOH), other ministries and agencies, and municipal governments, making efforts in human resource development. At present, however, there is a limit as to how far the MOH can manage all those efforts. The MOH intends to improve their disaster management capacity not only at the national government level but also at various local levels, and they hoped that Japan could assist them in developing their capacity building and training programs.

As for the introduction of universal health insurance, Myanmar has been trying to improve the accessibility to healthcare and quality of health of the public as a part of the reform agenda aiming to raise the overall level of social and economic growth. The then Myanmar President Thein Sein was promoting the reconstruction of healthcare sectors so that all citizens would have access to healthcare toward establishing a public health insurance system. The government developed various activities to achieve universal health insurance by expanding the existing healthcare programs. However, international procurement has not been possible due to the frameworks of supply chains for medical supplies and devices and management. Myanmar also needs a capacity building of healthcare staff to cope with international procurement.

The JMA expressed an intention to assist the introduction of universal health insurance and capacity building of healthcare staff in Myanmar from now on as a part of the JMA's international contribution in healthcare.

As for preparing disaster medicine programs, the Disaster Medical Assistance Team (DMAT) program, whose team members are physicians of large hospitals designated as the acute-phase disaster management institutions by the government to manage an acute phase of a disaster, and the Japan Medical Association Team (JMAT) program, which handles the post-acute phase, were introduced. The JMA suggested that the Myanmar MOH may be able to consult with the Japan Ministry of Health, Labour and Welfare (MHLW), which manages the DMAT program, for assistance in capacity building and other specific issues.

This meeting gave us hope that the JMA and the Myanmar Medical Association as well as the Japan MHLW and the Myanmar MOH will develop good relationships in both governmental and non-governmental sectors as we all work to realize the 2 healthcare targets of Myanmar.

The signing of the Agreements Between the JMA and the National Medical Associations Concerning Mutual Consent on Dispatching Physicians and Assistance Systems for Medical Relief Assistance in Disaster Situations

There was a colored-power explosion accident in a theme park in Taiwan on June 27, 2015, resulting in many young patients who were severely burned. Japanese burn experts were asked to assist in their care using donated artificial skins and medical supplies in July. Upon receiving requests for assistance from the Taiwan Medical Association and other parties, the JMA dispatched 6 burn experts recommended by the Japanese Society of Intensive Care Medicine, Japan Association for Acute Medicine, and Japanese Society for Burn Injuries as the JMA's "Joint Burn Care Assistance Team of Physicians by Three Medical Societies."

This accident led to further promoting civilian-based international cooperation in disaster medicine and relief efforts, and the JMA signed the Agreements Between the JMA and the National Medical Associations Concerning Mutual Consent on Dispatching Physicians and Assistance Systems for Medical Relief Assistance in Disaster Situations, with the Taiwan Medical Association and Taiwan Root Medical Peace Corps (a non-government organization in Taiwan for international disaster medicine assistance), respectively.

Takemi Program in International Health at the Harvard T.H. Chan School of Public Health

The JMA delegates visited Boston, USA, in June of 2015. During the visit, they were introduced to Associate Professor Jesse Boardman Bump (the 2010-2011 Takemi Fellow, USA) who was appointed as a new secretary-general of the Takemi Program in lieu of Professor Michael R. Reich, a directing professor of the program for many years, who would be on sabbatical for a year starting September of 2015. They also met Dean Julio Frenk and exchanged opinions on the evaluation and future framework of the Takemi Program and the successor of Professor

Reich. Dr. Yokokura expressed his wish to Dean Frenk that the person who replaced Professor Reich be expected to have an understanding of Japan and continue to work with the JMA in supporting the program. Dean Frenk expressed his strong intent to maintain the program with the support of the JMA for years to come, acknowledging that the Takemi Program has been active for over 30 years now, has produced fellows from over 50 nations, is unique in that the fellows study international and public health, and is highly appreciated within the Harvard programs.

A commendation ceremony was also held at the Consulate-General of Japan in Boston to honor Professor Reich for being awarded the Order of the Rising Sun, Gold Rays with Neck Ribbon in the Year 2015 Foreign Recipients of the Spring Imperial Decorations for his over 30 years of service as a directing professor of the Takemi Program and great contribution to the development of public and international health in Japan. A commemorative event was also held in Japan in July of 2015 at the JMA Building.

Japan Medical Association Junior Doctors Network (JMA-JDN) Activities

The JMA-JDN was established in October of 2012 to create a platform for promoting the activities of Japanese junior doctors both in Japan and abroad. The four missions of the JMA-JDN are to promote international activities, to foster cooperative learning among doctors regardless of their areas of specialization, to engage in active studies and make proposals concerning junior doctors, and to make contributions that reach regions and communities. The following is a report on the international and domestic activities for the current term.

International activities

With the support of the JMA, junior doctors now have the opportunity to participate in international conferences. Specifically, the JMA-JDN contributed to organizing the WMA-JDN meeting on April 27, 2014, which was held concurrently with the WMA Council Session in Tokyo. Seven members of the JMA-JDN participated and helped organize the meeting. At the meeting, the participants primarily exchanged ideas concerning the development of support systems

for pregnant and expecting doctors and the labor environment for junior doctors in each country. The JMA-JDN also had Dr. Masami Ishii, the Executive Board Member of the JMA, conduct a lecture concerning disaster medicine in Japan. His discussion of disaster management systems in Japan, which were developed from the foundation of the country's wealth of experience, gave great knowledge to the participants. On April 25, prior to the WMA-JDN meeting, the JMA-JDN guided participants on hospital visits. The JMA-JDN visited the Disease Control and Prevention Center at Japan's National Center for Global Health Medicine and exchanged ideas with participants concerning reporting systems for emerging/re-emerging communicable diseases as well as the systems of vaccination and measures against communicable diseases that are in place in various countries. Additionally, the JMA-JDN endeavored to introduce participants to Japanese culture such as sightseeing in Asakusa and Tokyo Tower and deepened international friendships through karaoke and visiting *izakaya* (Japanese-style tavern).

Two members of the JMA-JDN attended the WMA General Assembly in Durban, South Africa, held in October of 2014. At the time, the Ebola virus was ravaging various West African countries, and the general assembly provoked the JMA-JDN members to think of what junior doctors could do to assist with relief efforts. One JMA-JDN member attended the WMA General Assembly in Oslo, Norway, held in April of 2015. At the general assembly, the JMA-JDN reported their seminar plans, Japan-Korea exchange projects, participation in the Subcommittee Meetings for Junior Residents of the JMA Employed Physicians Committee, and the reality of the working environment for interns and young physicians in Japan, and won the 2nd place among the various countries in the presentation rankings. Three members attended the WMA General Assembly in Moscow in October of 2015. The WMA-JDN adopted the WMA Statement on Physicians Well-Being that was submitted during the WMA plenary session. Ever since its founding in 2010, the WMA-JDN had received many reports from various countries around the world concerning harsh labor conditions faced by junior doctors. The submission of this declaration resulted in a momentous event that, for the first time, reflected the consensus of the WMA-JDN

and marked the active resolution of a long debate. At the same general assembly meeting, the JMA-JDN once again received the prize for best presentation, and the group's foreign and domestic activities garnered global recognition. Additionally, the JMA-JDN Deputy Chair Chiaki Mishima came forward as a candidate for the Membership Director position of the WMA-JDN and was elected.

One member attended the CMAAO General Assembly in Manila, the Philippines, in September of 2014, and one member attended the CMAAO General Assembly in Yangon, Myanmar, in September of 2015. Since the WMA-JDN has few participants from the Asia-Pacific region, the JMA-JDN sent one member to visit South Korea in November of 2014 to start the Japan-Korea JDN Meeting with the goal of advancing medical knowledge exchange between closely neighboring countries in the region. In July of 2015, a member of the South Korean JDN visited Japan and exchanged ideas on mobile healthcare. Again, in January of 2016, 4 members of the South Korean JDN visited Japan and exchanged ideas on topics such as work-life balance, the system of medical specialty board, mobile healthcare, and maldistribution of doctors. In the Asia and Oceania region more junior doctors should be encouraged to participate in the October 2016 WMA General Assembly in Taiwan. The JMA-JDN will be collaborating with the WMA-JDN in an attempt to develop the Global Educational Exchange in the Medicine and Health Professions, a global program of exchange study for junior doctors.

Domestic activities

The JMA-JDN has also enriched its domestic activities in exchanging ideas and the understanding of junior doctors regarding the Japanese health care system and medical service. For example, JMA-JDN seminars were held to provide opportunities for co-operative learning regardless of areas of expertise, providing junior doctors with a broader perspective, and spurring growth. The JMA-JDN also held several workshops, such as the community medicine plan workshops in November of 2014 and June of 2015, a workshop on international health and universal health coverage, and the Japan Vision Health Care 2035 workshop held in February of 2016, which encouraged junior doctors to consider health care 20

years from now. In addition, the JMA-JDN works to co-sponsor seminars with regional junior doctors' groups to promote community activities by junior doctors. The JMA-JDN also took part in a residency meeting sponsored by the Tokushima Medical Association in April of 2015; the 11th Annual Gender Equality Forum held in Tokushima Prefecture in July of 2015; a mental health seminar sponsored by Education X Café, a young doctors group for mental health promotion among physicians and residents, in Osaka in October of 2015; and, finally, a conference for dialogue between medical students and residents sponsored by the Hokkaido Medical Association in February of 2016.

At the Subcommittee Meetings for Junior Residents, for both the 2014 and 2015 fiscal years, two members of the JMA-JDN served as the subcommittee members, and one member served as an observer. Those members endeavored to grasp the problems among residency training and the needs from junior doctors and were encouraged to give their candid opinions on various topics.

Even though the JMA-JDN's activities are supported by the JMA, unfortunately only a few junior doctors are members of the JMA. The JMA-JDN is actively recruiting additional junior doctors to join the JMA.

Future prospects

The JMA-JDN has actively participated in the WMA-JDN and CMAAO meetings with the support from the JMA, and the years of effort has won the trust of other countries. The JMA-JDN hopes to contribute to the operation of the WMA-JDN by continuing to produce its board members, and will share new developments surrounding junior doctors with other Japanese members as they learn from abroad and likewise strive to share any new developments surrounding junior doctors in Japan with the rest of the world. The JMA-JDN also wishes to lead the networking of junior doctors by closely cooperating with neighboring countries in the Asia-Pacific region.

As activities within Japan are necessary for international activities, the JMA-JDN will continue to provide domestic workshops and seminars. Of course, such activities will not end with merely having events; it is necessary to proceed in a manner that presents actual results, such as

putting together academic theses and proposals made from the consensus of junior doctors. As of February 28, 2016, the JMA-JDN has a network of 103 junior doctors. The JMA-JDN is now planning events that will utilize information technology and grass roots movements to create an environment where more junior doctors know and participate in JMA-JDN activities. Building more solid bridges is essential between the JMA and junior doctors.

The JMA-JDN is approaching its 4-year anniversary. To sustain the organization, it is necessary to construct a stable system that enables the seamless transfer of information to the next generation of JMA-JDN members. The JMA-JDN will start preparing for its next system and forming deep partnerships with the medical students who will lead the next generation.

Lastly, the JMA-JDN is grateful for the continued support and instruction from the JMA, which enables us to be a place for junior doctors to grow for many years to come.

Summary

The 4th term investigation topic was set as "the challenges of Japanese community medicine from the global health perspective." In other words, it means how much the Japanese medical community can benefit from health activities, which are, first, conducted on a global scale, and second, conducted in various local communities around the world. However, there is a strong nuance in global health that it covers public health in developing countries, and the various local communities (in the second point above) mean those of the developing countries. In this 4th term, the focus was emphasized on this area.

Concerning the world-wide activity, there are many lessons that can be learned from the WMA actions. We learn much also from WHO activities. These are learning activities that have been continued by the Global Health committee since the first term.

On the other hand, what about the secondly focused point? Initially, there were voices from the members of the committee that little lesson can be learned from community medicine of the developing countries. However, as explained above, from examples such as measures against infectious diseases, maternal and child health measures, disaster preparedness, and regional health measures, much lesson has been learned from all this.

As previously stated, even during the times of financial difficulties, Japan was successful to establish cost-effective and efficient healthcare systems for the "community." Japan's financial situation gets much better now but still we can learn something meaningful from the developing countries. In these countries, human resources such as doctors and nurses in public health are also lacking. Money is lacking. Materials are lacking. However, as in Japan, every life should be saved. In the health care activities conducted in all-lacking communities, we can gain native knowledge and wisdom. It is not about the resources, but about the wisdom.

Doctors working in the community should have such wisdom and understanding. Knowledge and wisdom will be communicated to a different area once it is first born. For instance, why not put aside the differences between the work of a hospital-based medical doctor and a community-based medical practitioner. If the hospital-based clinical department and community-based practitioners come together, the community medicine design will be feasible. Secondly, with the spirit of professional autonomy, we will be able to reach out to a wider field. Finally, in the "Community-based Comprehensive Care system," just as "one should be able to live where they are used to living for their whole life," people such as doctors should have a sense of duty and act in a way in which the people are expecting. To be able to influence the system and people, we should behave appropriately with insight and foresight on top of understanding the full situation.

The knowledge and wisdom borne in one community should be wisely used in the other communities. Through various network opportunities, a unique community medical care activity can be spread across the world. Thereby, such community action network can bring about outcomes that are comparable to those obtained from the use of Big Data.

Slow pace is fine, as long as it is a steady progress. And, if it is firmly acknowledged in a community, we call it a success.

As Mahatma Gandhi says, *"Good travels at a snail's pace. Those who want to do good are not selfish, they are not in a hurry, they know that to impregnate people with good requires a long time."*

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Analysis of Free Legal Counselling for the Great East Japan Earthquake and the Outlook for the Field of Disaster Recovery and Revitalization Law

Tadashi OKAMOTO[1]

Abstract

Of the free legal counselling conducted by lawyers following the Great East Japan Earthquake, the results of analysis of approx. 40,000 cases have been disclosed by the Japan Federation of Bar Associations. These analysis results have been used as evidence serving as the basis for system revision and new legislation following the disaster, and have been of value to public policy, to a certain extent. In order to identify methods for realizing policy targets as know-how for public policy through the integration and analysis of legal needs in disaster areas, in FY2012 and thereafter, lectures on the "Disaster Recovery and Revitalization Law" were initiated by the Graduate School of Public Policy, Chuo University; Keio University Law School; and other institutions. Under the Disaster Recovery and Revitalization Law, new public policy education fusing various fields of government, policy, law, disaster prevention and crisis management, etc. has been implemented. By utilizing the database on free legal counselling, it may be possible to identify legal systems that need to be ironed out or problems related to public policy in preparation for a huge disaster such as an earthquake directly striking the Tokyo metropolitan area or an earthquake in the Nankai Trough. It is thought that intensifying study of relevant fields will result in the proposal of new designs in the fields of disaster prevention and crisis management.

Key words   Disaster Recovery and Revitalization Law, Public policy, Disaster prevention education, Crisis management, Analysis of free legal counselling, Great East Japan Earthquake

Introduction

For victims of and business operators affected by the Great East Japan Earthquake and the Fukushima Daiichi Nuclear Power Plant Accident,[1] lawyers conducted a large number of free legal counselling sessions beginning just after the disaster in cooperation with the Japan Federation of Bar Associations (JFBA), the Bar Associations of various regions, the Japan Legal Support Center, other professionals with expert qualifications, companies, NPO corporations, and other private support groups, etc. At the suggestion of the Author, the results of this counselling were tabulated by the JFBA, leading to the creation of a free legal counselling information database comprising approx. 40,000 cases. The results were summarized in the "Analytical Results of the Great East Japan Earthquake Free Legal Counselling"[2] and "Examples of Great East Japan Earthquake Free Legal Counselling."[3]

This paper will add simple explanations about the respective trends in legal needs in each of the areas affected by the Great East Japan Earthquake and commentary thereon; the contribution of legal needs analysis results in the revision of laws or design of systems after the

[1]   Partner, Ginza Partners Law Office. Visiting Professor, Graduate School of Chuo University. Lecturer, Keio University Law School. Tokyo, Japan (tadashi@law-okamoto.jp).

disaster; the proposal by the Author concerning a "Disaster Recovery and Revitalization Law as public policy study," and the results thereof; and further activation methods, and the significance thereof, provided in the free legal counselling database (which has been made available to the public) that have been clarified in the reports related to free legal counselling mentioned above; and the process of preparing these reports, etc. Details are provided in "Promotion of the Disaster Recovery and Revitalization Law" (Okamoto, 2014).[4]

Results of Analysis of Information from Free Legal Counselling

The areas affected by the tsunami following the Great East Japan Earthquake extend along the Pacific Ocean coast from the Tohoku Region to the Kanto Region. In addition, there was earthquake damage-including that caused by the main shock and aftershocks—over a broad range of urban areas. Furthermore, the area to which residents were forced to evacuate due to the accident at the Fukushima Daiichi Nuclear Power Plant is vast. Therefore, depending on the form of the disaster and the form of the impact of the disaster on individuals and corporations, the needs of victims varied. In this section, I will analyze the disaster area of the Great East Japan Earthquake from the aspect of legal needs.

Methods of legal needs analysis

Here I will briefly describe legal needs analysis methods. For details, please see the references mentioned above (Okamoto, 2014).

First of all, as indicated in **Table 1**, I added some phenomena unique to the Great East Japan Earthquake to the types of legal counselling provided by lawyers under normal circumstances, creating 24 types, and then classified the subjects (issues) of the free legal counselling carried out at evacuation shelters or other counselling facilities in the disaster area, or via telephone counselling or other methods, into the relevant types. I then calculated the percentage of all counselling in each area that comprised a single type of counselling. This is the volume of "legal needs" in each area. As I decided to classify one free legal counselling subjects into three counselling types at a maximum, the total counselling ratio exceeds 100%. In addition, out of the individual items, **Table 2** shows model cases of major legal counselling subjects that account for a large percentage of counselling in each area.

Legal needs differ for each area

(1) Trends in legal needs in Iwate Prefecture overall

Figure 1 shows the percentage of subjects (issues) of legal counselling received by consulters whose addresses at the time of experiencing the disaster were located in Iwate Prefecture out of the total number of legal counselling cases recorded in the database approx. one year after the disaster.

These results are characterized by large ratios for "16. Wills/inheritance" (25.6%), "12. Disaster laws and regulations" (24.5%), and "9. Loans or leases of houses, vehicles, ships, etc." (11.3%). This trend can be analyzed in simple terms as a reflection of the devastating tsunami damage to cities and settlements in ria coastline areas of Iwate Prefecture and supports the fact that the form of disaster is deeply reflected in the problems of individuals and companies (that is, legal needs). However, it is possible to say that policies for rebuilding or revitalization that rely on not only the form of the natural disaster, but also revitalization policies and/or support methods covering the legal needs of individuals and companies and the kind of damage they experience are required.

(2) Trends in legal needs in Miyagi Prefecture overall

Figure 2 shows the percentage of subjects (issues) of legal counselling received by consulters whose addresses at the time of experiencing the disaster were located in Miyagi Prefecture out of the total number of legal counselling cases that were recorded in the database approx. one year after the disaster.

Trends that were not observed in Iwate Prefecture as shown in **Fig. 1** are large ratios for "5. Real property lease," (20.8%), and "6. Liability of possessors and owners of structures and disputes" (9.1%). In simple terms, these trends can be considered to be a reflection of the urban area of Sendai City, which has a population of 1.03 million, experiencing damage in the earthquake and tsunami. In urban areas, there are more lease agreements for offices and houses, and in the maintenance of daily living—not only due to the devastating damage from the

Table 1   The 24 types of free legal counselling subjects (issues)

No./Classification	Subject
1. Ownership of real property (including loss of ownership)	• Primarily issues of ownership concerning loss or destruction of land and buildings, registration of loss of buildings, loss of registration certificates, etc. are classified in this category. • Issues of loans for destroyed residences are placed in Item 9. • Issues of damage compensation, rights of claim against owners of neighboring land, etc. to the elimination of obstructions, etc. caused by damaged property are classified under Item 6. • Issues of government benefits for damaged residences, etc. are classified under Item 12. • Issues concerning risk sharing due to destruction of objects after completion and before delivery of newly-built buildings, or after closing of real estate purchase agreements and before the delivery thereof, are classified under Item 20.
2. Ownership of vehicles, ships, etc. (including loss of ownership)	• Primarily issues of ownership concerning loss or destruction of cars or ships, etc. and damage compensation issues, etc. concerning damage to cars in storage, etc. are classified under this category. • Issues of loans and leases for destroyed cars or ships, etc. are classified under Item 9. • Issues of non-life insurance of cars, etc. are classified under Item 11.
3. Current assets such as deposits and shares, etc.	• Issues of loss, etc. of bankbooks and securities, etc. are classified under this category.
4. Real property lease (leased land)	• Issues concerning land lease agreements are classified under this category.
5. Real property lease (leased houses)	• Issues concerning building lease agreements are classified under this category.
6. Liability of possessors and owners of structures and disputes (obstruction elimination, prevention, damage compensation)	• Issues of structural liability (damage compensation); issues due to destruction of land and buildings; damage compensation issues concerning water leaks, etc., of multi-occupancy housing; and other neighboring relationship-related issues are classified under this category.
7. Land boundaries	• Issues of cost allocation concerning destruction of boundaries, determination of boundaries, etc., are classified under this category.
8. Debt collection (loans, accounts receivable, contracting, etc.)	• Issues concerning collection of claimable assets are classified under this category.
9. Loan or lease of houses, vehicles, ships, etc.	• Issues concerning loans and leases of houses, cars and ships are classified under this category.
10. Payment of other loans	• Issues concerning borrowings other than those classified under Item 9 are classified under this category.
11. Insurance	• Issues concerning nonlife insurance (fire insurance, earthquake insurance, automobile insurance), life insurance, and mutual-aid insurance, etc. are classified under this category.
12. Disaster laws and regulations (legal interpretations, etc. concerning accreditation by public benefit corporations or the government, etc.)	• Application and legal interpretation of earthquake-related laws such as the Act on Support for Reconstructing Livelihoods of Disaster Victims or the Disaster Relief Act, receipt of livelihood protection, receipt of donations, temporary housing, and legal interpretation of various government accreditations are classified under this category.
13. Taxes	• Tax-related issues are categorized under this category.
14. New loans	• Issues concerning the new financing system and the application and interpretation, etc. of earthquake-related laws concerning loans are classified under this category.
15. Divorce/relatives	• Issues between relatives and guardianships, etc. in relation to disasters are classified under this category.
16. Wills/inheritance	• Issues concerning wills, inheritance, disappearance adjudication, and the legally presumed death system, etc. are classified under this category.
17. Consumer damage	• Issues concerning consumer damage in relation to disasters are classified under this category.
18. Labor issues	• Issues concerning employer-employee issues concerning employment agreements and unemployment insurance, etc. are classified under this category.
19. Foreign nationals	• Issues unique to foreign nationals are classified under this category.
20. Risk-bearing, commercial or corporate issues	• Issues unique to companies and business operators, and issues of risk sharing in relation to the destruction of objects, etc. in sale and purchase agreements, etc. are classified under this category.
21. Criminal issues	• Issues concerning criminal matters are classified under this category.
22. Nuclear power plant accident, etc.	• Issues concerning accidents at nuclear power plants, etc. are classified under this category.
23. Others	• Contents of counselling that do not fall immediately under Item 1 to 22 are classified under this category.
24. Non-disaster issues	• Contents of counselling that have no or little relationship to disaster are classified under this category.

Table 2   Major legal counselling subject model cases

Legal counselling subject	Model case
5. Real property lease (leased houses)	• A rental house was destroyed by the tsunami and became uninhabitable. Is it necessary to keep paying rent? • There are some cracks on the wall due to the earthquake. Who has the obligation to repair this, the landlord or the renter? Is there any financial support? • The house is still usable and livable, but since we do not have the money to rebuild, we have been asked to move out. Is this proper? • When we move out of the house due to the complete destruction of the building, can we get our deposit back? Or can we get forced removal compensation?
6. Liability of possessors and owners of structures and disputes (obstruction elimination, prevention, damage compensation)	• The roof tiles of my private house fell off due to the earthquake and damaged the neighboring house or walls of the neighboring house or the neighbor's automobile. Are we liable for the damage? • The walls of a store collapsed and automobiles parked in parking lot were damaged. Can we make a claim for damages against someone? • If there is water leakage from the upper floors of a condominium, who is liable?
9. Loans or leases of houses, vehicles, ships, etc.	• The land and buildings of my private house were washed away due to the tsunami. I also lost my workplace so I cannot pay my housing loan. Is there any support for rebuilding? Will the existing loans remain unless I declare bankruptcy? • Do we have to keep paying the housing loan on a house that is uninhabitable due to instructions to evacuate because of the nuclear power plant accident, etc.?
12. Disaster laws and regulations	• What kind of procedures are necessary to receive support money for reconstructing the livelihoods of disaster victims? In what cases is it possible to obtain a disaster-victim certificate? When and how can we obtain one? • Is it possible to obtain a disaster-victim certificate and receive support money for reconstructing the livelihoods of disaster victims even when the victims are living in rental housing? • I find it unacceptable that we are certified as being in the same household with my parents, who are on a separate household budget, based only on what is written on the resident certificates, and that we will only receive support money or donation amounts for a single household. • Although my brother, who was my only living relative and with whom I had been living for several decades years, is deceased due to the earthquake, disaster condolence money is not paid to siblings under the legal system [at that time]. I cannot understand this. • I received notification from the government that if I receive support money or a donation, livelihood protection will be cut. Is this true?
16. Wills/inheritance	• Many family members and relatives have died. Who will be the inheritor? If there are missing persons, what kind of procedures should we take? Opinions differ even within the family on whether or not to apply for death registration for missing family members. • I heard that if we do not do anything for three months after the death of a family member, we will inherit the loans as well, so we need to waive the inheritance. However, first of all, it is unclear what kinds of assets the deceased family member had, or what will happen with real estate in areas washed away by the tsunami, so we cannot decide on whether or not to waive inheritance. • There are likely to be disputes over the allocation ratio of support money or donations with inheritors living in distant areas. However, we lost everything in the tsunami and we do not even have a means of transport, so there is no way at all that we could appear in court.

tsunami—people tend to have numerous issues in relation to such agreements. There were many cases of consultations concerning urban earthquake damage in Miyagi Prefecture overall. However, with regard to lease agreements and neighboring relationships, what should be noted here is that in actuality the voices of disaster victims in coastal areas have been drowned out by the voices of consulters in urban areas. The coastline of Miyagi Prefecture has ria coasts in the north and broad plains in the south, and both regions were significantly affected by the tsunami. However, since the populations in these areas are not necessarily large, the legal needs of

[Note] 1. The data is based on the number of free legal consultations provided in affected areas (from mid-March to late-May, 2012).
2. The common denominator used to calculate the percentage of each category was 4,925.
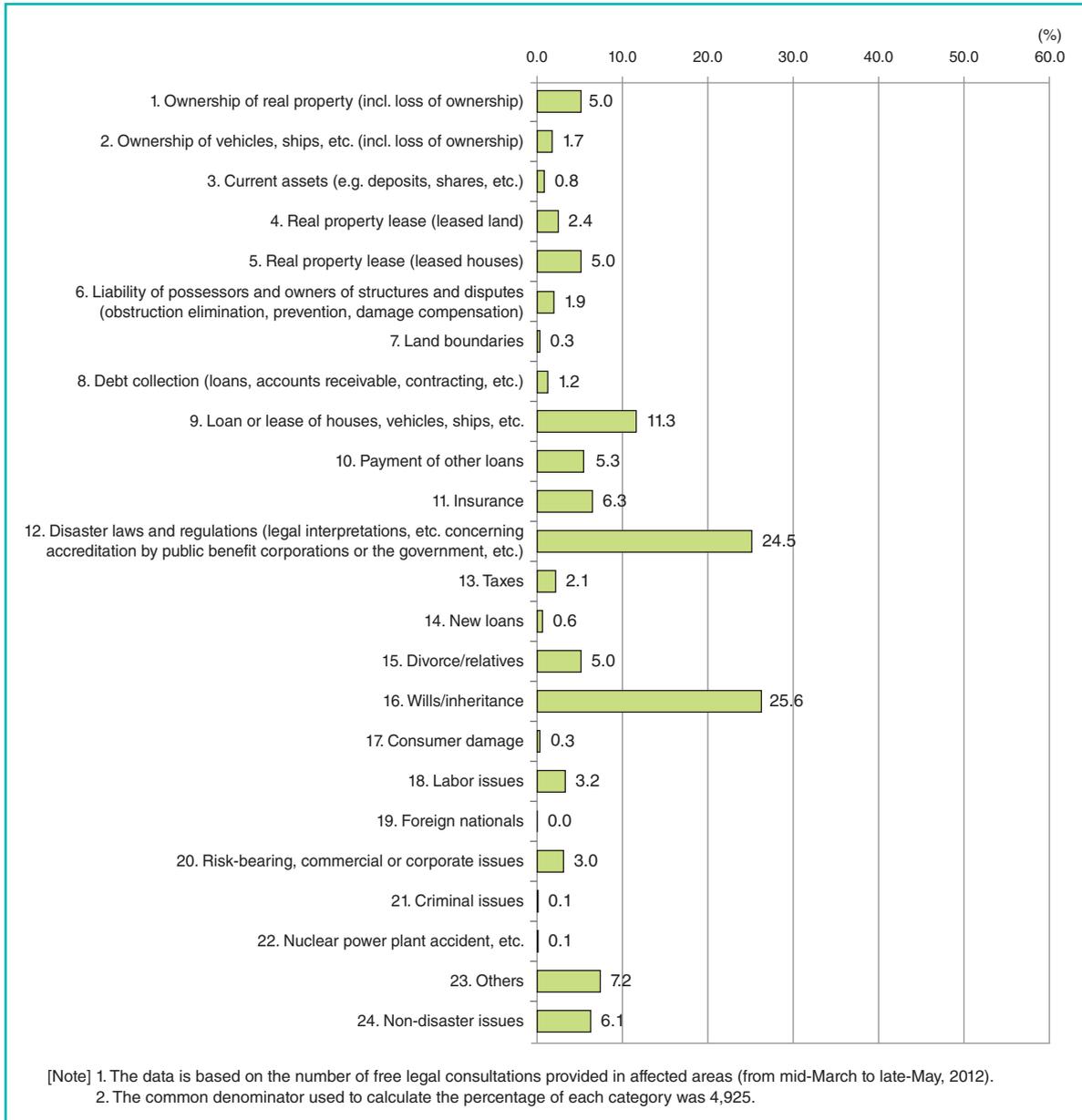
Fig. 1 Subjects of free legal counselling (Iwate Prefecture overall)

coastal areas are not apparent in the statistics for Miyagi Prefecture overall. Therefore, the coastal areas of Miyagi Prefecture must be separated from the urban areas (the areas without tsunami damage) in the analysis of legal needs. It is not possible to list all of the data on coastal areas in this paper due to space limitations, so please refer to the "The Encouragement of the Disaster Recovery and Revitalization Law" (Okamoto, 2014) for a complete list.

(3) Trends in legal needs in Fukushima Prefecture overall
Figure 3 shows the percentage of subjects (issues) of legal counselling received by consulters whose addresses at the time of experiencing the disaster were located in Fukushima Prefecture out of the total number of legal counselling cases that were recorded in the database approx. one year after the disaster.

These results are characterized by the over-
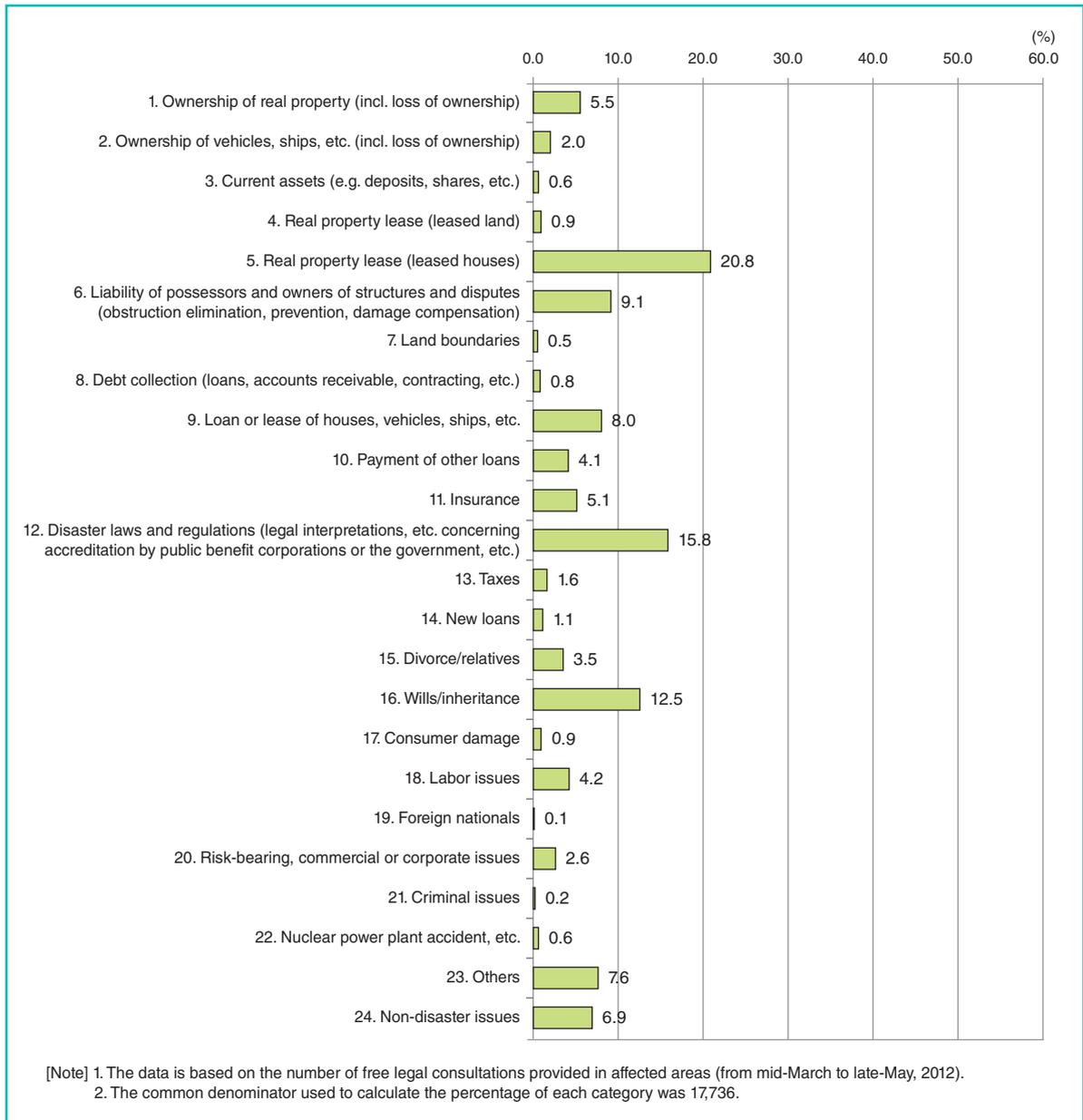
Fig. 2 Subjects of free legal counselling (Miyagi Prefecture overall)

whelmingly large ratio for "22. Nuclear power plant accident, etc." (55.1%). This trend indicates the magnitude of the number of consulters who were affected by the accident at the Fukushima Daiichi Nuclear Power Plant. This number forces us to think deeply about the impact of the nuclear plant accident on Fukushima Prefecture. Although the analysis results strongly reflect the impact of the nuclear plant accident, percentages for "5. Real property lease" (7.5%), "Liability of

possessors and owners of structures and disputes" (6.3%), and "9. Loans or leases of houses, vehicles, ships, etc." (7.0%) are not necessarily low, either. Of the large cities of Fukushima Prefecture, there was huge earthquake damage to buildings in Fukushima City and Koriyama City, and in coastal areas of Iwaki City, a significant degree of tsunami damage was also observed. Therefore, it is possible to conclude that there have been many problems related to lease agree-

[Note] 1. The data is based on the number of free legal consultations provided in affected areas (from mid-March to late-May, 2012).
2. The common denominator used to calculate the percentage of each category was 12,294.
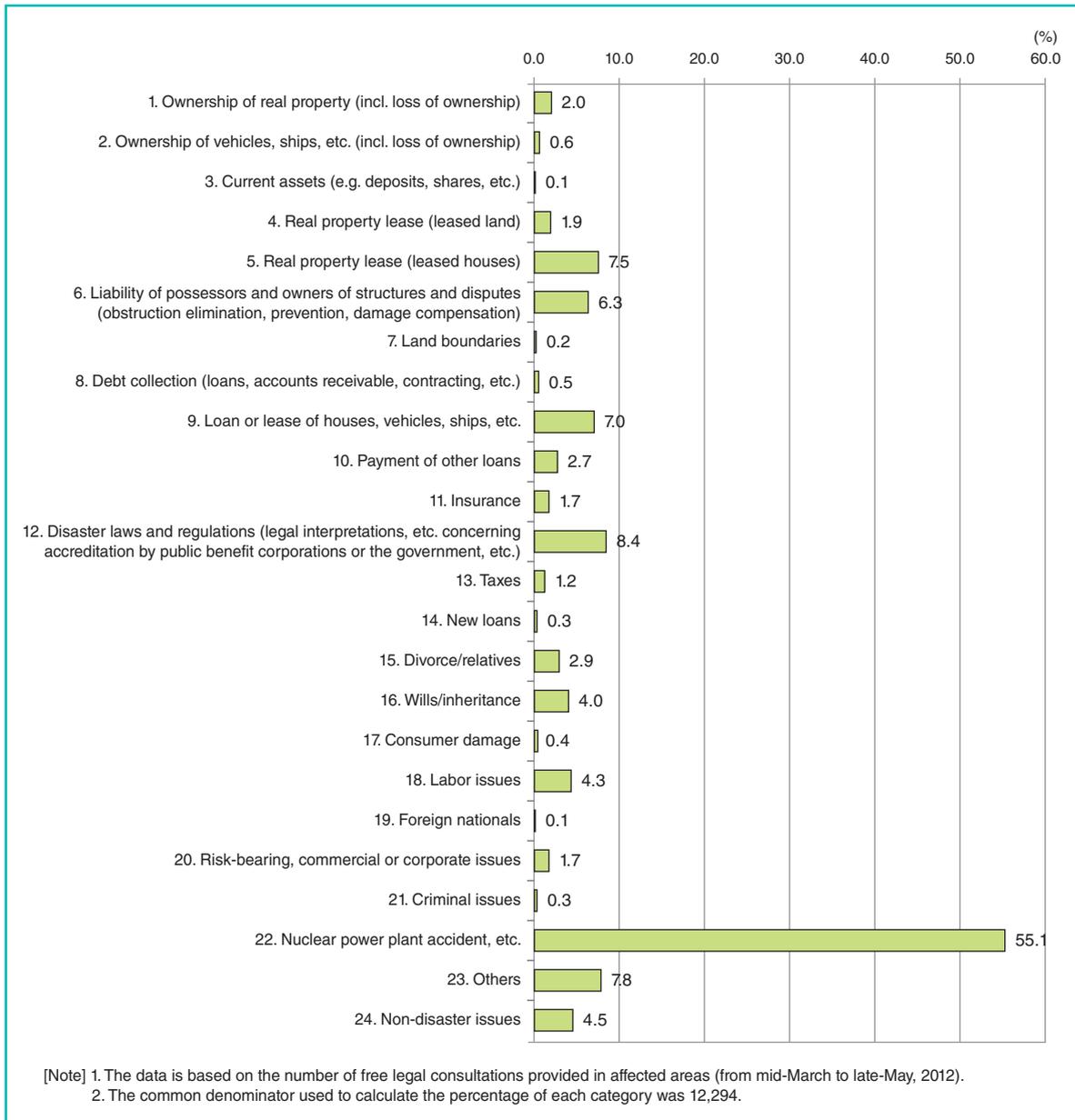
Fig. 3   Subjects of free legal counselling (Fukushima Prefecture overall)

ments or neighboring relations in urban areas.

It must also be noted that, amongst the consultations concerning housing loans, in addition to consultations on whether it is necessary to keep paying a housing loan on a house or business premises damaged by the tsunami, there were also many consultations regarding whether or not it is necessary to keep paying loans for houses that are uninhabitable due to instructions to evacuate because of the nuclear power plant

accident.

Legal needs change as time passes

Figures 1, 2, and 3 show the results of classification of free legal counselling cases collected during a period of approx. 1 year following the Great East Japan Earthquake disaster. However, the problems of victims and affected companies have been constantly changing since the disaster occurred. This is also reflected in changing legal
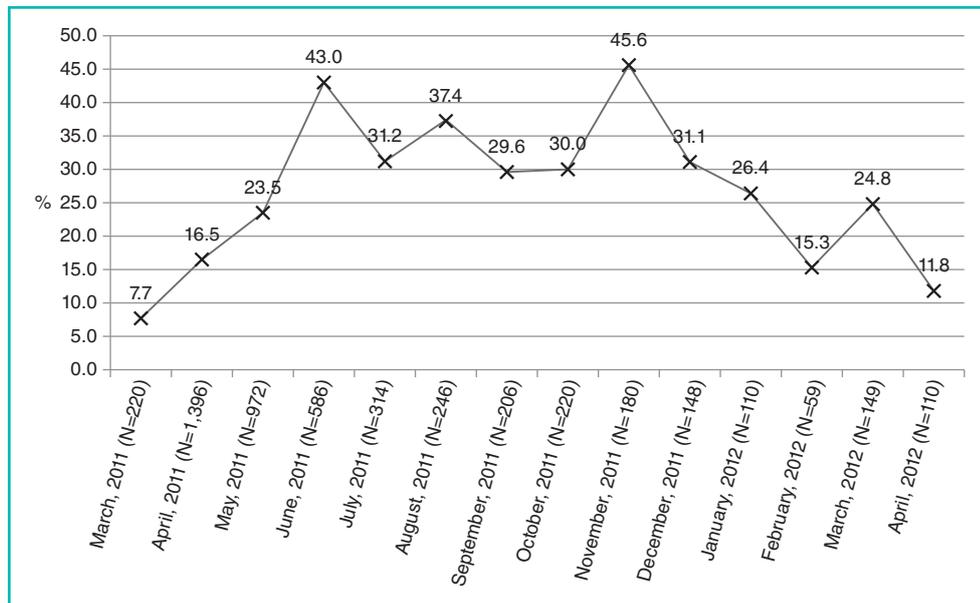
Fig. 4 Monthly changes in the ratio of consultations related to inheritance
(Iwate Prefecture; "16. Wills and Inheritance")

needs.

Figure 4 shows how the percentage of legal counselling received by consulters whose addresses at the time of experiencing the disaster were located in Iwate Prefecture changed on a monthly basis out of the consultation subjects classified under "16. Wills and inheritance."

In March 2011—just after the earthquake—the percentage of consultations concerning inheritance was 7.7%, which is much smaller than the cumulative total of 25.6% for Iwate Prefecture overall (Fig. 1). However, this percentage increased rapidly, rising to 16.5% in April and 23.5% in May, and reaching as much as 43.0% in June. This is thought to reflect the psychological state of people whose family members had died or were missing (three months is generally regarded as the length of time needed to accept the death of intimate persons). Another factor was the tremendous impact of time limitations imposed on renouncing inheritance under the inheritance system set forth in the Civil Code, etc. Under the Civil Code, there is a system for renouncing inheritance (complete renunciation of the inheritance rights and obligations of the inheritor).

The period in which the renunciation of inheritance is possible is stipulated as being within 3 months of becoming aware of the death of the inheritee (this period is called the cooling-off period). After this period has passed, renunciation of inheritance becomes impossible, and inheritors will inherit all of the rights and obligations of the inheritor. If the inheritee had a large amount of liabilities that exceed their assets and an inheritor desires to renounce the inheritance, it is necessary to carry out renunciation procedures during the cooling-off period, or apply for an extension of the period during the cooling-off period. If it is discovered that an inheritee died on March 11, the final date of the cooling-off period for the bereaved inheritors is June 11. Thus as June approached, legal needs involving the need to renounce inheritance rapidly increased.

Legal needs concerning the nuclear power plant accident, etc.

Figure 5 provides a more detailed breakdown of the percentage of legal counselling received by consulters whose addresses at the time of experiencing the disaster were located in Fukushima Prefecture out of the total number of legal counselling cases during the approx. 1 year following the disaster and that were classified under "22. Nuclear power plant accident, etc." (No overlap-

(N=4,454)

Entrance into Evacuation/No-Entry Zones 0.6%
Education 0.4%
Stolen Property/Custodial Respnsibility 0.8%
Business Continuation/Asset Management 0.5%
Various Procedures 1.1%
Other 3.2%
Damage by Rumors 0.7%
Government's Policies and Proposals 1.1%
Radioactivity 2.2%
From Lessors 1.5%
From Lessees 2.8%
Living as Evacuees 6.3%
Contracts 7.5%
Compensation for Damage 71.3%

[Note] 1. The subjects of this analysis were those who had addresses in Fukushima at the time of the earthquake.
2. "N" means the number of legal consultations.

Fig. 5   Breakdown of consultation subjects concerning "22. Nuclear Power Plant Accident, etc." (Fukushima Prefecture)

ping classification results).

The percentage for "Damage compensation" (71.3%) is overwhelmingly large as a consultation category. This is thought to be due to the fact that, since the legal counselling was provided by lawyers, many people came for counselling with claims for nuclear damage in mind from the beginning. As the "Act on Compensation for Nuclear Damage" stipulates that business operators have liability at the time of the occurrence of a nuclear accident, it is thought that from the very start many victims of the nuclear power plant accident had a common understanding that damages could be recovered by claiming compensation against the obligor.

Reasonable rates were also observed for "Agreement-related" (7.5%), "Evacuation life" (6.3%), "Consultations from lessees" (2.8%), and "Consultations from lessors" (1.5%). Although it is impossible to tell from **Fig. 5**, in actual fact the percentages for the top three consultation subjects in April 2011 were "Damage compensation" (31.6%), "Agreement-related"

(21.4%) and "Evacuation life" (16.9%), and the combined total number of consultations for "Agreement-related" and "Evacuation life" was greater than the total for "Damage compensation."[4] Legal needs for nuclear damage compensation did rise tremendously, even from the start; however, it is possible to conclude that the nuclear power plant accident inflicted various problems on victims in addition to damage compensation issues, including the consequences of various agreement relationships, problems related to dispute resolution, and matters arising as a result of evacuation life. This indicates that the resolution of damage compensation disputes alone cannot resolve the legal needs of victims, and rebuilding their lives or recovery and revitalization cannot be achieved.

Locus of the Realization of Policies and Contribution of Information Obtained from Free Legal Counselling (Value as a Database in Verifying the Existence of Legislative Facts)

Table 3 provides a list of records of system revisions or new legislation that have been achieved and that originated from proposals by the JFBA, Bar Associations of individual areas, and volunteer legal professionals, etc., based on the legal needs of victims and affected companies that were identified through free legal counselling following the Great East Japan Earthquake.[5]

The realization of various policies cannot be achieved through the power of lawyers alone. These are systems born out of cooperation and negotiations with many stakeholders. In order to realize policies, legal needs that have come to light through the results of analysis of free legal counselling provided by lawyers are thought to provide persuasive support for promoting the revision of systems for various types of stakeholders as "legislative facts" (social realities that serve as the basis for the justifiability of systems or laws).

Creation of Disaster Recovery and Revitalization Law as a Part of New Disaster Prevention Education

Significance of disaster recovery and revitalization law as university education

With regard to the work of gathering and analyzing information from free legal counselling conducted in disaster areas and formulating proposals for policies using the statistical data created therefrom, efforts to realize policies using bottom-up methods from the needs in the actual disaster zone constitute know-how that should be fully utilized at the time of a major disaster or crisis in the future.

Underlying that fact it was possible for this many policies to be realized in the Great East Japan Earthquake were the activities of lawyers in the Great Hanshin-Awaji Earthquake (1995) and the Niigata Chuetsu Earthquake (2004). In the Great Hanshin-Awaji Earthquake, too, solutions to double loan issues, improvement of the direct benefit system, and resolution of other issues were requested by lawyers; however, many of these requests ultimately were not formalized

into legal systems. Meanwhile, issues and know-how from the times of these respective disasters remained with the lawyers and government administrative officers who had gained experience in policymaking at those times. This fact enabled swift and accurate formulation of proposals and policies at the time of the Great East Japan Earthquake.

As a disaster-prone country, Japan must face the risk of the occurrence of huge disasters—even after experiencing the Great East Japan Earthquake. The probability of the occurrence of an earthquake directly striking the Tokyo metropolitan area, or an earthquake in the Nankai Trough, has been increasing each year. In preparation for such disasters, it is considered necessary for us to receive the legacy of know-how for realizing policies by summarizing, focusing on the opinions of victims and affected companies after the occurrence of a gigantic disaster.

The Author feels that research institutions such as universities, etc. are appropriate vessels for transmitting wisdom over the medium-to-long term. At the Keio University Law School, a course on the Disaster Recovery and Revitalization Law was newly instituted and commenced in April 2012. In addition, the university's Faculty of Law also introduced a course entitled "Disaster Recovery and Revitalization Studies I and II" in April 2013. Moreover, policy formulation know-how is well-suited to the field of public policy, and lectures on disaster recovery and revitalization law were initiated in April 2013 at the Graduate School of Public Policy, Chuo University.[6]

"Disaster Recovery and Revitalization Law" has not been systematically organized as an academic field, and it is incomplete. I anticipate that research on public policy approaches originating from legal needs will become more extensive in the future.

Significance of disaster recovery and revitalization law as disaster prevention education, general knowledge, and corporate training

Disaster recovery and revitalization law does not comprise research or illustration (elucidation) of any special field at times of emergency. To use an abstraction, it can almost be said to be a mere repositioning of the normal policy formulation process in order to analyze the needs of indi-

Table 3 Primary system revisions and new legislation originating from proposals by legal professionals

Building of a system for the reduction of or exemption from disaster loans
In order to solve the problem of "double loans," we asserted that a disaster loans purchase and reduction or exemption system must be newly established; consequently, the "Guidelines for Individual Debtor Out-of-Court Workouts" (a system for the reduction of or exemption from disaster loans for individuals) and the "Act on the Incorporated Organization for Supporting the Turnaround of Businesses Damaged by the Great East Japan Earthquake" (a business rehabilitation system for business operators that includes the purchase of debts) were established. In addition, we requested thorough familiarization with the disaster loan reduction or exemption systems, and the Financial Services Agency issued notification to financial institutions requesting thorough familiarization therewith, following which financial institutions familiarized victims via notification postcards.

Extension of the cooling-off period for renunciation of inheritance, etc.
As the "within 3 months" set forth in the Civil Code is too short, we requested an extension of up to one year for the cooling-off period for renouncing inheritance. Consequently, the "Act on Special Exceptions to the Civil Code Pertaining to the Period in which Inheritance Acceptance or Renunciation must be Performed Resulting from the Great East Japan Earthquake" was enacted as a bill sponsored by lawmakers, and it was determined that the cooling-off period would be extended to November 30, 2011. In the disaster-affected areas, cases of renunciation of inheritance or application for extension of the cooling-off period increased drastically.

Inclusion of siblings among the eligible recipients of disaster condolence money and donations
Siblings were not included amongst eligible recipients for disaster condolence money; however, the Act to Revise a Part of the Act on Provision of Disaster Condolence Grant—which includes siblings who lived with or were under the same household budget with the victim—was subsequently enacted. In addition, some municipalities in the disaster-affected areas changed their bylaws in response to the enactment of this law. With regard to the distribution of donations also, siblings were formerly excluded as eligible recipients for grants; however, at the prefectural level there was a response to enactment of the law to expand the framework to include siblings.

Disaster condolence money to be classified as credit for which attachment is prohibited
Since it was formally possible for creditors to attach disaster condolence money, we requested that disaster condolence money be classified outside the target for attachment, and a law prohibiting attachment was enacted as a bill sponsored by lawmakers.

Act on Support for Reconstructing Livelihoods of Disaster Victims
With regard to the support system for reconstructing the livelihoods of disaster victims, which provides grants of up to 3 million yen to the households of victims, we asserted that the 50% assistance ratio set by the government should be increased drastically; subsequently a special measures law was enacted to increase the government assistance rate to 80%.

Non-application of the Act on Temporary Treatment of Rental Land and Housing in Cities Damaged by War
Considering the actual situation of consultations concerning lease agreements, setting of preferential land lease rights and so on by application of the Act on Temporary Treatment of Rental Land and Housing in Cities Damaged by War might possibly interfere with town building. As a result of discussions with the Ministry of Justice and the Ministry of Internal Affairs and Communications, which had been considering application of the Act, it was ultimately decided that the Act did not apply to the Great East Japan Earthquake.

Nuclear Accident Child Victims' Support Act
By summarizing various needs arising from the nuclear power plant accident, we contributed to the enactment of the Act Concerning the Promotion of Measures to Provide Living Support to Victims, Including Children Who Were Affected by the TEPCO Nuclear Accident in order to Protect and Support Their Everyday Lives. Proposing concrete measures based on this support act has become a new mission for legal professionals.

Basic Act on Disaster Control Measures 2013 Revision
Based on the present situation in which rescue and support for people in need of support in times of disaster or people evacuated from larger areas becomes difficult due to supporters non sharing personal information on victims from municipalities, the Japan Federation of Bar Associations submitted related opinions and formulated guidelines for sharing personal information, also holding a symposium on "proper handling of personal information at times of disaster" for familiarization and putting together a nationwide campaign that was linked to a major revision of the Basic Act on Disaster Control Measures. This had a major impact on the personal information measures of municipalities, such as systemization of their "List of people in need of support in conducting evacuations," "Safety information," and "Victims' ledger."

Extension of extinctive prescription for right of claim for compensation for damages relating to nuclear damage
This is an epoch-making special measures law that is potentially applicable on a million-person scale. The "Act on Measures to Realize Early and Definite Compensation Pertaining to Nuclear Damage Arising from the Accident at the Nuclear Power Plant in the Great East Japan Earthquake and Special Exceptions on Extinctive Prescriptions, etc. of the Right of Claim of Compensation Pertaining to Nuclear Damage" extends an extinctive prescription (which is set at "3 years" under the right of claim for damages due to tort) to "10 years" and the statute of limitations (which is set at "20 years from the time of the tort") to "20 years from the time of occurrence of damages."

Realization of deregulation to promote land expropriation for revitalization sites
The Act to Revise a Part of Act on Special Zones for Reconstruction in Response to the Great East Japan Earthquake came into effect on May 1, 2014. In the disaster area of the Great East Japan Earthquake, there are many land sites targeted for revitalization projects whose acquisition has not proceeded smoothly due to the disappearance of the owner, unprocessed inheritance, or land sharing by a large number of persons, and swift acquisition thereof has become an urgent task. Through this Act, relaxation of the requirements for land expropriation judgment procedures, or the requirements for disaster prevention group transfer projects, etc., were recognized as a legal system.

viduals and companies in the actual disaster zone and use this analysis for policy proposals for the actual disaster zone. Devising how to create a new system with what kind of ideas is not necessarily a field where only law-related specialists excel, and can extend beyond the limit of legal interpretations. Therefore, disaster recovery and revitalization law is regarded as a field with a sufficient number of additional uses as a topic for training or workshops, or simply general knowledge.

Moreover, disaster recovery and revitalization law can also be described as "disaster prevention education." Normally in "disaster prevention education," training to protect people immediately after the occurrence of an earthquake, or education to foster judgment ability regarding tsunami evacuation presuming the occurrence of a tsunami, are regarded as the mainstream fields (workshops for creating hazard maps are conducted in these fields). The aim of both fields is learning techniques to protect people from the vast forces of nature.[7,8]

However, the threat of disaster is not limited to the instant when natural forces strike cities or people. When a person's life is saved and the person moves to an evacuation site, the phases of "staying alive," "rebuilding lives," and "carrying out revitalization" begin. When a person experiences damage or the loss of many assets or even family members, in some cases they will have a greatly increased need to request systematic support information on how to make the first step forward. If a person has no knowledge about support systems, the lack of knowledge itself may cause the person to lose assets or their health. Psychologically as well, the person may be in a state of mind close to despair.

Under disaster recovery and revitalization law programs, methods for providing information to transform the despair of disaster victims into hope is also considered to be an important issue requiring examination, and results have been observed to a certain extent. To acquire the knowledge necessary for a person to get back on their feet immediately after suffering and surviving a disaster is regarded as a type of "disaster prevention education."

Remaining Legal Needs Analysis Problems and Significance

Analysis at the municipality level

The results of the analysis of legal needs (**Figs. 1-4**) presented in this paper are simple graphs created against the large framework of prefectural results for free legal counselling. Of course, it is possible to glean a great deal of information from these results; however, I am not exempt from criticism that they lack precision to some extent with regard to accurately comprehending legal needs with a focus on individual persons and corporations. For the "Analytical Results of the Great East Japan Earthquake Free Legal Counselling"[2] report mentioned above, analysis was carried out as far as possible at the level of the municipalities in which the addresses of the consulters at the time of experiencing the disaster were located. It is easy to surmise that legal needs will differ depending on whether the address is in a coastal area with a low population or a heavily populated area, or an urban area that experienced the earthquake and not the tsunami. It is indispensable to evaluate data broken down to at least the municipality level.

It is also indispensable to examine the relevant analysis results at the municipality level together with time lapse changes. Analyzing how legal needs change with the elapse of time and comparing the differences that have arisen depending on the individual municipality could present an opportunity to identify policies that are inadequate for a particular municipality. Moreover, it is possible to examine whether or not the impact of information provision by the central government or the revision of systems reflects the legal needs that were recorded through the free legal counselling.

Plot analysis of public and administrative agency data and legal needs

When the characteristics of legal needs at the municipality level have been identified, it is then useful to perform analysis examining the correlation of these results with other statistical data. This means forming hypotheses regarding the correlation between such factors such as population density, damage prediction, age composition, and industry composition and legal needs that become apparent through free legal counselling at times of huge disasters, and to examine
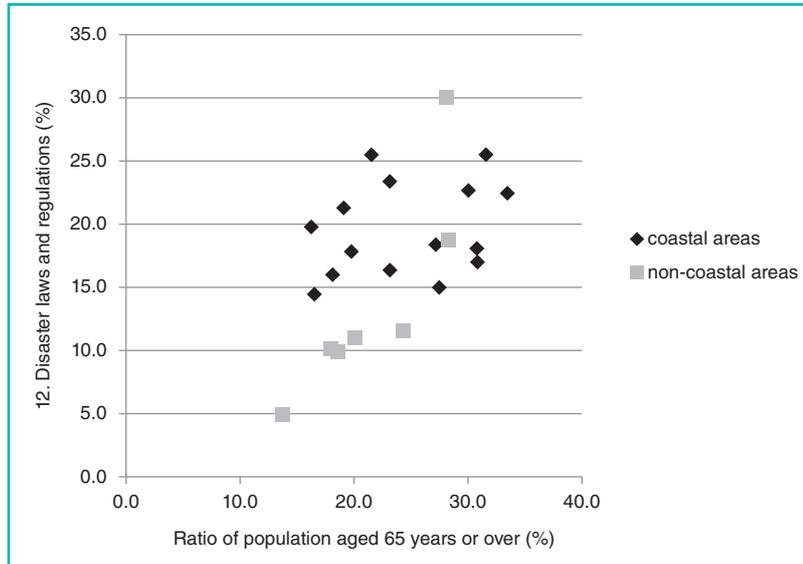
Fig. 6   Correlation between percentage of consultations for "12. Disaster laws and regulations" and "Ratio of population aged 65 years or over"

Photo 1   Lecture on disaster recovery and revitalization law (Keio University Law School, 2014)

these.[9,10]

Figure 6 plots individual municipalities in Miyagi Prefecture, with the percentage of consultations for "12. Disaster laws and regulations" for each municipality (which was calculated from the results of analysis of information from the free legal counselling conducted after the Great East Japan Earthquake) on the vertical axis and the corresponding "Ratio of population aged 65 years or over" for municipalities in Miyagi Prefecture (coastal areas (◆), and non-coastal areas (■); data based on the 2010 Census by the Ministry of Internal Affairs and Communications) on the horizontal axis.

From **Fig. 6**, it can be seen that in municipalities where the percentage of the population aged 65 years or over is higher, the percentage of consultations concerning "12. Earthquake-related

laws" is higher. It can also be seen that this trend does not depend on whether or not the municipality experienced the tsunami. Consultations concerning "12. Disaster laws and regulations" are, simply put, administrative consultations concerning various support systems for which procedures must be carried out at the municipal office in each municipality (support money for reconstructing livelihoods of disaster victims, disaster condolence money, donations, livelihood protection, temporary housing, etc.). It is probable that, since it is difficult to communicate such information to elderly persons, the provision of support information by lawyers increased as the elderly population percentage increased.

As seen here, by plotting the percentage of consultations with other statistical data, it is possible to visualize correlations that could not be perceived before. If these correlations are applied to municipalities where a huge disaster is predicted to occur, it may be possible to "predict legal needs (damage)," leading to proposals for support systems to be constructed. It is the Author's hope that these results will be used as guidelines for addressing various issues that should be dealt with immediately after a disaster where crisis management measures are being formulated, including disaster prevention planning by government institutions or corporate BCP.[*1]

Conclusion

In this paper, I discussed the process and results of analysis of information from free legal counselling that was carried out after the Great East Japan Earthquake and the locus for using these results in reforming the disaster revitalization law system. In order to convey this information as know-how for public policy, an academic field called "disaster recovery and revitalization law" is in the process of being established, although the field is still in its early days (**Photo 1**). Analysis of free legal counselling information and positioning of disaster recovery and revital-

ization law as an academic field are still in the process of development, and work has yet to start on a large number of problems. As people living in the present era, we have the responsibility to safe-guard the precious data obtained from the individual voices of victims and lessons learned from the disaster as memories for all of humanity in later generations. I hope that there will be greater recognition of the necessity for further analysis and systematic organization of "disaster recovery and revitalization law"as an academic field.

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*1 BCP: Business Continuity Plan.

Large-scale Health Information Database and Privacy Protection[*1]

Ryuichi YAMAMOTO[1]

Abstract

Japan was once progressive in the digitalization of healthcare fields but unfortunately has fallen behind in terms of the secondary use of data for public interest. There has recently been a trend to establish large-scale health databases in the nation, and a conflict between data use for public interest and privacy protection has surfaced as this trend has progressed. Databases for health insurance claims or for specific health checkups and guidance services were created according to the law that aims to ensure healthcare for the elderly; however, there is no mention in the act about using these databases for public interest in general. Thus, an initiative for such use must proceed carefully and attentively.

The PMDA[*2] projects that collect a large amount of medical record information from large hospitals and the health database development project that the Ministry of Health, Labour and Welfare (MHLW) is working on will soon begin to operate according to a general consensus; however, the validity of this consensus can be questioned if issues of anonymity arise. The likelihood that researchers conducting a study for public interest would intentionally invade the privacy of their subjects is slim. However, patients could develop a sense of distrust about their data being used since legal requirements are ambiguous. Nevertheless, without using patients' medical records for public interest, progress in medicine will grind to a halt. Proper legislation that is clear for both researchers and patients will therefore be highly desirable.

A revision of the Act on the Protection of Personal Information is currently in progress. In reality, however, privacy is not something that laws alone can protect; it will also require guidelines and self-discipline. We now live in an information capitalization age. I will introduce the trends in legal reform regarding healthcare information and discuss some basics to help people properly face the issue of health big data and privacy protection with a sense of ownership.

Key words   Big data in health field, Large-scale health information databases, Privacy,
The Act on the Protection of Personal Information, Secure computing

Overview and Problems of Health Big Data

When we talk about health big data, it can be rather difficult to understand what the term actually means. So, I would like to start by giving a clear overview of health big data and its problems.

People often say that we now live in a data-oriented age. I will give you a brief overview of what this actually means and introduce some of the preparations currently being made toward
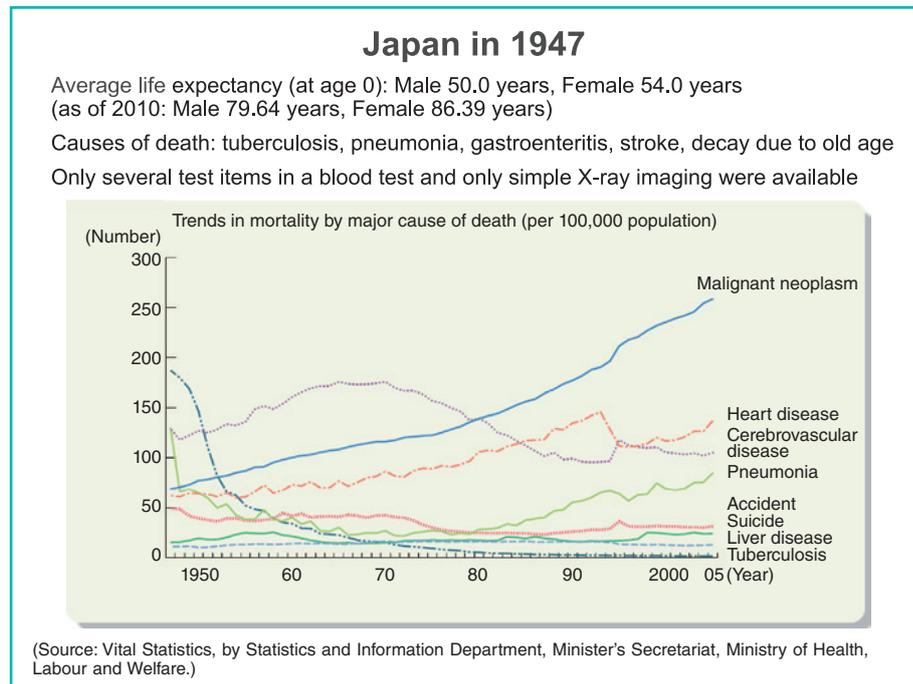
Fig. 1   Japan in 1947 and trends in mortality by major cause of death

establishing health information databases in Japan.

I will also discuss what legislation will be required and then go into detail regarding various informatics measures that should be promoted, including possible data management options and what more can be done in terms of informatics measures.

The Disappearance of Large Amounts of Medical Information

As everyone probably knows, 1947 is the year that the Constitution of Japan came into effect (**Fig. 1**). Article 25 of the Constitution states "All people shall have the right to maintain the minimum standards of wholesome and cultured living."

So, what was 1947 like? The number one cause of death was tuberculosis, followed by pneumonia and gastroenteritis. So, the top 3 causes of death were all infectious diseases. Stroke was ranked the 4th and the 5th was decay due to old age. Most of these conditions progress quickly and usually resulted in death. The medical technology available back then was limited;

only simple X-ray imaging was available, and blood tests were simple ones such as counting blood cells under a microscope or reading the blood sedimentation rate. The average life expectancy at age 0 in 1947 was 50 years for men and 54 years for women. These figures, however, already exceeded 80 in 2010.

The top 3 causes of death have also shifted to malignant neoplasm, heart diseases, and cerebrovascular diseases. Heart diseases and cerebrovascular diseases are essentially the end results of lifestyle-related diseases. Malignant neoplasm, or simply cancer, is often said to have progressed for more than 10 years before it is found, and many patients must endure many years of cancer treatment. In other words, people do not die quickly from cancer. The 4th greatest cause of death, pneumonia, is quite different from what it was back in 1947, as you already know. The next one is accidents, followed by suicide. Thus, it is evident that most of the current leading causes of death are diseases with very long courses.

I made a request to an organization related to the Ministry of Internal Affairs and Communications so that I could investigate what kinds of information concerning medical care and
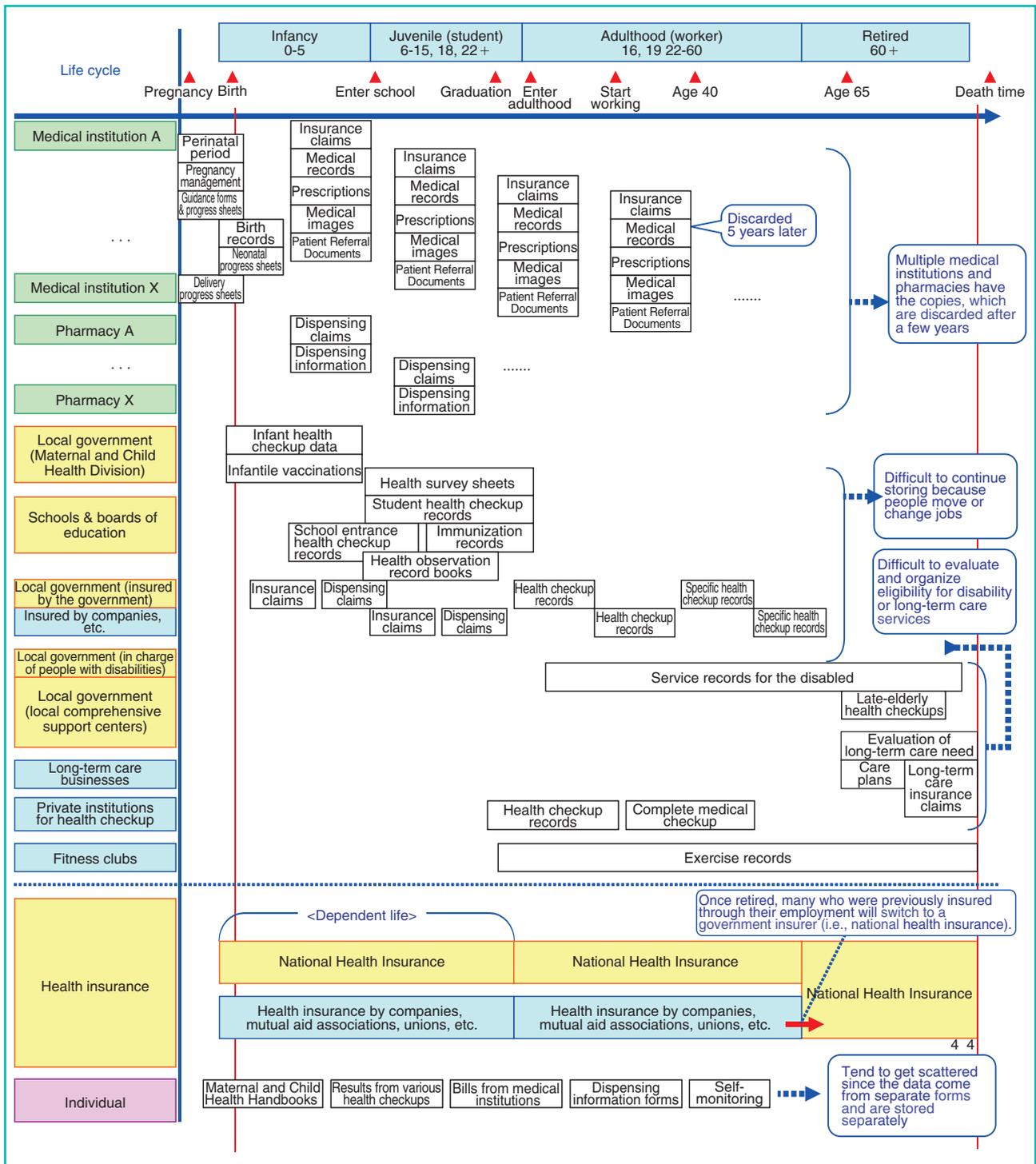
Fig. 2 Medical and health care information produced in life

health are produced in one's life. There are indeed various sorts of information (**Fig. 2**).

The problem, however, is that all this infor-

mation often disappears altogether, or it is somewhere that the individual does not know and thus has no way of accessing. In essence, a large
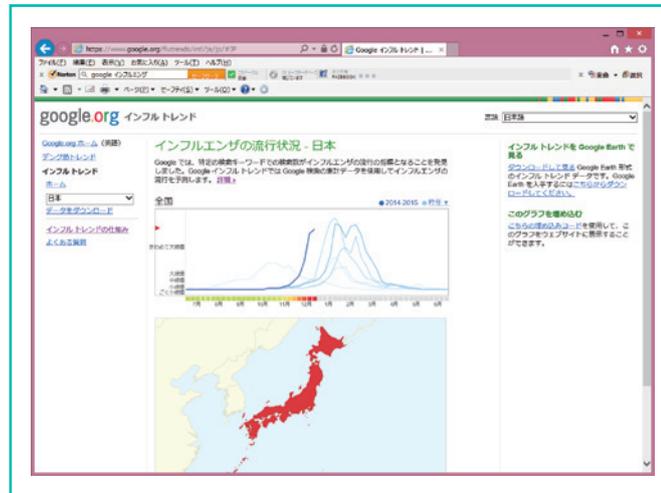
Fig. 3 Influenza outbreak trends in Japan by Google

amount of information is produced but completely disappears. Thus, deciding policies relating to research, medical care, and health in this situation is quite a challenge.

Finding New Value by Capitalizing a Large Amounts of Data

Of course, dealing with large amounts of data using analog methods such as an abacus or lined sheets of papers manually is impossible to begin with; the handling of a large amount of data was made possible by computer technology and IT advancements.

In January 2011, during a popular television quiz show "Jeopardy!" in the US, a computer system called WATSON, created by an American IT company, won against human opponents. This was the first time that a computer system had won against a human in a knowledge-based competition. It was quite the news.

Actually, WATSON was not really developed by the IT company; it was the result of a collaboration between informatics experts all over the world. What WATSON does is read vast amounts of available documented information scattered across the Internet in various natural languages, process this information—not online but in an isolated environment—and analyze it earnestly to derive knowledge. This is what WATSON did to win the quiz show.

In this quiz show, panels are shown to all participants and a presenter asks participants to choose a question depicted in the panel—for example, "The number 30 in 'politics,' please." There was a similar quiz show in Japan, wherein the text of the questions was often not stated in an easily comprehensible manner and could be quite confusing even for humans. Still, WATSON won.

At present, the IT company in question is focusing on WATSON's application in medical areas, and is independently conducting empirical projects at institutions such as the University of Pittsburgh.

Figure 3 shows Google Flu Trends, which first started when researchers began estimating the number of people with influenza using Google search data. Now, it incorporates other various factors in the prediction. This work has become somewhat world-famous since it allows prediction of specific local flu trends sooner than does fixed-point monitoring.

So, we are now capable of processing more and more data. So, what can we do with such a large amount of data? This is the essence of the concept of big data. In reality, big data analysis is still in its infancy, and not many attempts are currently in progress. However, there is no doubt that new projects are being developed one after another.

Twelve years ago in the US, this kind of poster was quite popular (**Fig. 4**). "Data is the New Oil." For someone like me, who learned classical English grammar, this phrase "Data *is*" draws the attention a bit. Anyways, the point of
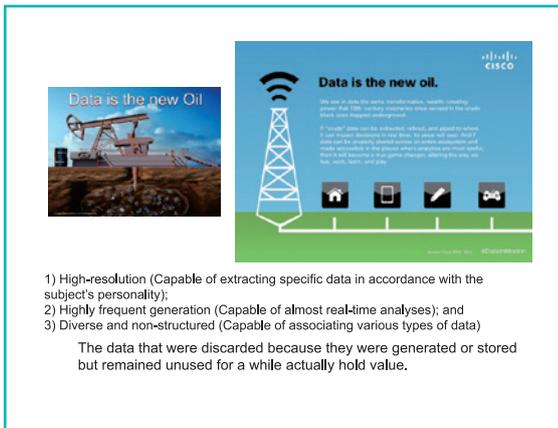
Fig. 4   This kind of poster was popular in the US twelve years ago

1) High-resolution (Capable of extracting specific data in accordance with the subject's personality);
2) Highly frequent generation (Capable of almost real-time analyses); and
3) Diverse and non-structured (Capable of associating various types of data)
 The data that were discarded because they were generated or stored but remained unused for a while actually hold value.

Fig. 5   Examples of healthcare databases in Japan

Data-oriented Age

> National Insurance Claim and Health Check-up Database (DB) (*aka* NDB)
> Mid-Net Project (PMDA & MHLW)
> KDB
> Long-term Care Need Evaluation DB
> National Cancer Registry
> Cardiac Catheterization DB
> Heart Failure Case DB
> National Clinical DB
> ·······

such a poster is that data has been thrown away because we had no way to keep it. By capitalizing on it, we can give it new value. Data capitalization is the keyword of the present era, and that is why the current age is called the data-oriented age.

Development Status of Databases in Japan

So, are there any databases on healthcare in Japan? Actually, yes.

In terms of IT development in healthcare fields, Japan was in the top position until about 2000 or so, thanks to all the forerunners in the IT area. Every medical institution had a computer, for financial processing for national health insurance claims to the government. No other country had almost all of its medical bill information in an electronic form in one way or another.

The issue of social security is, of course, an urgent matter in many countries, and there has been a trend to introduce IT and streamline social security systems. However, few of those involved in introducing IT to social security had thought of accumulating and capitalizing on data, save for some notable trailblazers.

Then, things began to change around 2005 or so. We had planted the seeds of IT development in healthcare, so why not harvest the fruits as well? The tendency to accumulate and analyze

data was suddenly growing, along with the urge to accomplish something. The databases shown in **Fig. 5** have already been developed or are being developed.

The first one is what we commonly call the "National Database (NDB)," or the national health insurance claim and health check-up database, of the Ministry of Health, Labour and Welfare (MHLW). I will discuss this in more detail later since I serve as the chairman of the Assessment Committee on the evaluation of database use.

The second, MID-NET*3 Project lead by Pharmaceuticals and Medical Devices Agency (PMDA) and MHLW's Safety Division is a database of drug safety events from 10 million people or so, which will contain data not from the claim data but from electronic medical records and service/test ordering systems from medical institutions; furthermore, it will include information such as all test results. This project aims to discover less common side effects to drugs more quickly.

KDB is also a database of national health insurance (*Kokuho*, for short). Unlike the MHLW's database (NDB), KDB puts some burden on local governments. Furthermore, this database is linked to databases for nursing care services, which contain information almost entirely extracted from the elderly. The linked database is already operational as a tool to analyze geriatric medical and long-term care, and local governments have started to use it.

*3 MID-NET: Medical Information DB NETwork.

By combining Big Data and new IT technology
including natural language analyses, we can ...

- Discover new medical knowledge
- Provide advanced monitoring for home patients and others
- Provide tailored services
- Create new service industries
- Achieve Japanese-style sustainable social security

If it is available, we would like to make use of Big Data now,
but otherwise, we would make use of it in the near future ...

Challenges we must face include...
- Linking databases with different purposes (common ID)
- Privacy protection in a data-oriented age
- Re-distribution of values

Fig. 6   Possibilities and challenges concerning health big data

The Nursing Care Need Evaluation DB is also done electronically from the beginning, and the information is all in the database. The National Cancer Registry, which will begin in 2015, will also be in a database, and the Japanese Circulation Society is in the process of developing databases for cardiac catheterization and heart failure cases. I hear that they already have data on quite a number of cases. Listed next is the National Clinical DB, which is the database managed and used by various surgical societies. This one was created many years ago, and they have since accumulated a considerable number of cases.

Issues to Be Solved Concerning Health Big Data

Although these databases and the information contained within are not fully standardized, they show some potential through IT techniques including natural language analysis. We all want to make use of what is available. Evidence-based policymaking and healthcare will be more important in the future, so databases will definitely have a role to play. However, the use of databases is not to be taken lightly, and there are still some challenges to be resolved (**Fig. 6**).

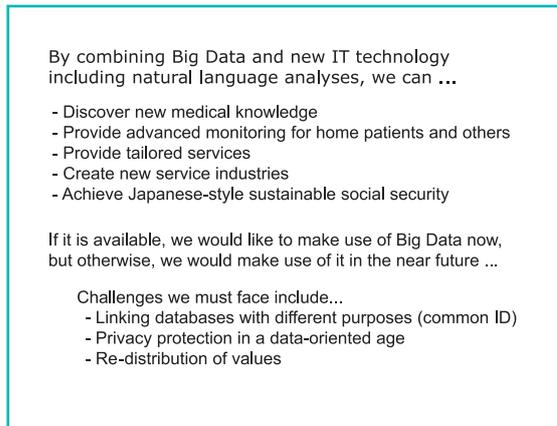The National Cancer Registry, for example, will register any cancer case once a diagnosis is made, but will still only include one main treatment and the rest is untouched. This cancer registry, which begins later this year, is based on current law and will cross-reference with the

Basic Resident Register (*Jumin Kihon Daicho*). So, we would be able to tell from the database if a person dies, but we will not be able to find the details of the treatment he/she received before passing away.

If this database were to be connected with the NDB, we would be able to tell what kind of care a patient received after their diagnosis until they passed away. The data will not include test results, but the medical services he/she received will be available from the linked database. At present, however, there is no means of connecting these databases.

If possible, this information should be integrated and analyzed to produce better results. A common ID system would be necessary for that purpose. On the other hand, it would mean that someone could find almost all of an individual's medical information using these databases. We cannot deny the possibility that such information would be used to violate individuals' rights or for discrimination.

Therefore, there are challenges in considering what privacy protection is appropriate for such a data-oriented age (**Fig. 6**). The "re-distribution of values" is listed at the bottom, but I would like to skip this part today.

Utility Value and the Characteristics of a Large-scale Health Database

I would like to quickly introduce the NDB, which was designed in 2006 and has been accumulating data since 2009 (**Fig. 7**). This database, which can be used both online and offline, contains all data from health insurance claims and specific health check-up and guidance information in an electronic form. I was part of the discussion briefly when the design of this database was still being debated, and I can tell you that the data are processed before storage so that patients' identities cannot be traced.

The NDB was created according to the Act on Assurance of Medical Care for Elderly People and the law ordains its use for optimization of healthcare expenses. Thus, application of its pre-determined use generally proceeds smoothly, but this database can be utilized for other various purposes, too.

Those who wish to use the database for purposes other than those for which it was intended must first apply to the database's authority, after
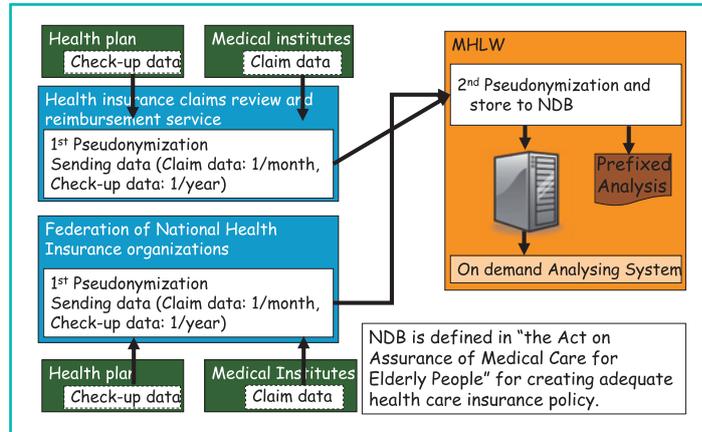
Fig. 7 National Health Insurance Claims and Health Check-up Database (NDB)
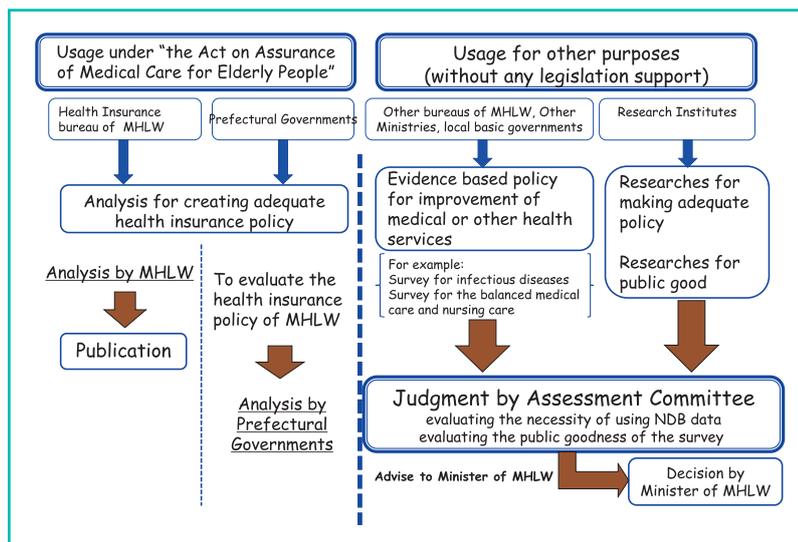
Fig. 8 Usage of NDB

which the public interest and data safety of the stated use will be fully reviewed before any data are disclosed. Meetings by experts, called the Assessment Committee, are held to evaluate these uses and offer advice to the Minister of Health, Labour and Welfare (**Fig. 8**).

So, what do the data include? All information from health insurance claims are included with the identities removed. The insurance policyholder's number, his/her date of birth, and gender are all erased in one step by creating 1 hash value from these 3 numbers. This is done using an encryption program to create a short string of numbers from a longer string—in our case, the number created is still quite long.

Another value is then produced by transforming the policyholder's name, date of birth, and gender into a single value. This transformed value cannot be transformed back into the original numbers (policyholder number, date of birth, and gender); however, the original and the transformed values match nearly one-to-one.

These 2 hash values, which I will call the ID number for now, will be used in the database. The patient's gender can be determined from the ID, but not his/her policy number or date of

Fig. 9   Data included in NDB

birth. The ID number of the medical institution is included in health insurance claims and specific health check-up data (**Fig. 9**).

To put it shortly, such a database is very comprehensive. In Japan, over 95% of health insurance claims and almost 100% of prescription data exist in an electronic format. Dental claims, which were once a little behind in digitalization, have recently been rapidly catching up, and the database containing such claims now covers almost all people in Japan. Such nationwide databases are relatively common in Asian countries. South Korea and Taiwan started a little earlier than Japan did. Each nation's database is unique, but I will not go into details here since there is little point in it.

Types of Databases and System Management

So, how big is the NDB now? It now contains data from 8 billion insurance claims and close to 100 million specific health check-up and guidance cases (**Fig. 10**).

Because this database is quite heavy and troublesome to handle, 2 subsets were developed for convenience. One is commonly referred to as the "sampling dataset," and consists of a random sample of 1% of outpatients and 10% of inpatients, for which health insurance claims over 1 month and prescription claims for the same

Fig. 10   Present Status of NDB

month and the following month are consolidated.

Among these, uncommon data such as rare diseases, rare medical practices, or rarely prescribed medicines and medical supplies—all occupying less than 0.1% of the data—are replaced with dummy data. As such, about 90% of disease names, 80% of medical practices, and 90% of prescriptions and medical supplies are omitted from the data subset. The remaining data in the subset, which consequently only comprise common diseases and procedures, are then replaced with dummies and made available for approved users.

The second subset is called the "basic dataset." This also comprises sampling data, but the data from insurance claims for the same persons are all linked. This subset is made from a sample of about 5% of the claims, and it is currently available for use. Starting from April 2015, on-site research centers become operational.

In the health insurance claim data, the names of policyholders are erased but can be easily guessed for certain people. The database allows physicians to follow up on someone with a very rare disease for an extended period of time. So, for example, one would be able to tell which month a patient went to see a physician over a 5-year period. Someone close to this patient, say a daughter, would be able to infer that the data is maybe that of her father. Therefore, the database is made available to individuals only on the premise that it will be securely managed because the data are not completely anonymous.

However, this "fully secure data management" cannot be easily achieved by most researchers or the general public. We frequently decline applicants for not filling out the items on secure management properly in the application forms.

The on-site research centers will provide secure management for data, so that people could conduct their research by visiting a center and looking up the data. There are 3 locations—2 in Tokyo and 1 in Kyoto—and they have been operational since April 2015. People can look up data quite freely at these centers, but no data can be brought outside.

If someone wants to bring the data out of the center, he/she must fill out an application, claiming that "I processed the data these ways and created such and such datasets, and I would like the copies." The dataset requested will not be readily available at the center; the requested dataset will be re-extracted by the center staff to verify its safety before it is given to the applicant.

To further protect the privacy of the data in the on-site research centers, a PPDM*4 system, which is actually an umbrella term, is expected to be introduced at some point in the future so

that center users can analyze data while ensuring data privacy.

What Can We Tell from Health Insurance Claim Data?

So, what can we tell from health insurance claim data? **Figures 11 and 12** show the data based on a test study that a member of the Assessment Committee conducted by filing an application for the current NDB use to make sure that the application procedures we developed would actually function properly.

These charts illustrate the relationship between the Secondary Healthcare Zones and inpatients' diseases. In **Fig. 11**, for example, the darkest blue is the north Kyushu Healthcare Zone. This shows the proportions of inpatients in the north Kyushu Healthcare Zone who actually live in that area.

So, we can tell that most brain infarction inpatients come from the same healthcare zone. For breast cancer, however, the figure is very different (**Fig. 12**). Not many breast cancer patients are going to medical institutions in the same healthcare zone in which they live. This means that many are going outside of their own Secondary Healthcare Zone.

This study on health insurance claim data suggests that the concept of the Secondary Healthcare Zone should be seriously re-evaluated for some diseases. This is just an example of what health insurance claim data can tell us.

Protection of ID and Privacy by Legislation

We need proper legislation for the protection of ID information and privacy in order to use these data without unjustly discriminating against patients or the medical institutions that provided data.

For ID data, MHLW has already started reviewing several possibilities for capitalizing on the numbering system in healthcare. This numbering system*5, which begins in October 2015, is very similar to Taxpayer Identification number

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*4 PPDM: Privacy-Preserving Data Mining.

*5 Since October, 2015, Individual Numbers (nicknamed "My Number") have been issued to residents in Japan under the Social Security and Tax Number System. "My Number" is required for administrative procedures related to social security, taxation, and disaster response, beginning in January, 2016. http://www.cas.go.jp/jp/seisaku/bangoseido/english.html.
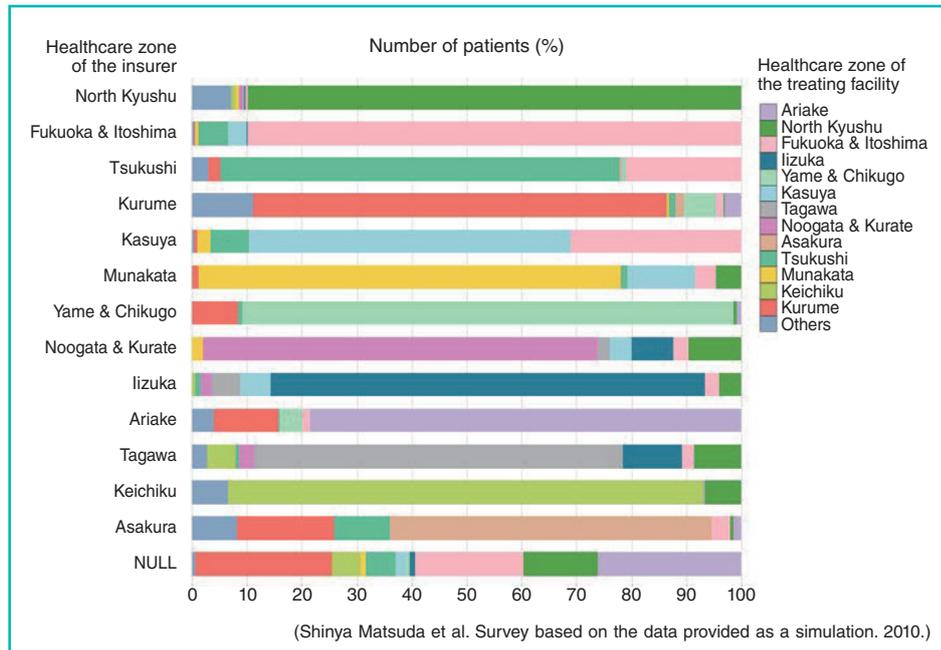
Fig. 11 Healthcare zones in which patients received care by the zones in which they reside
(Cerebral infarction; all ages; inpatients; national health insurance; Longevity Health Plan; and social welfare programs in total; shown in %)
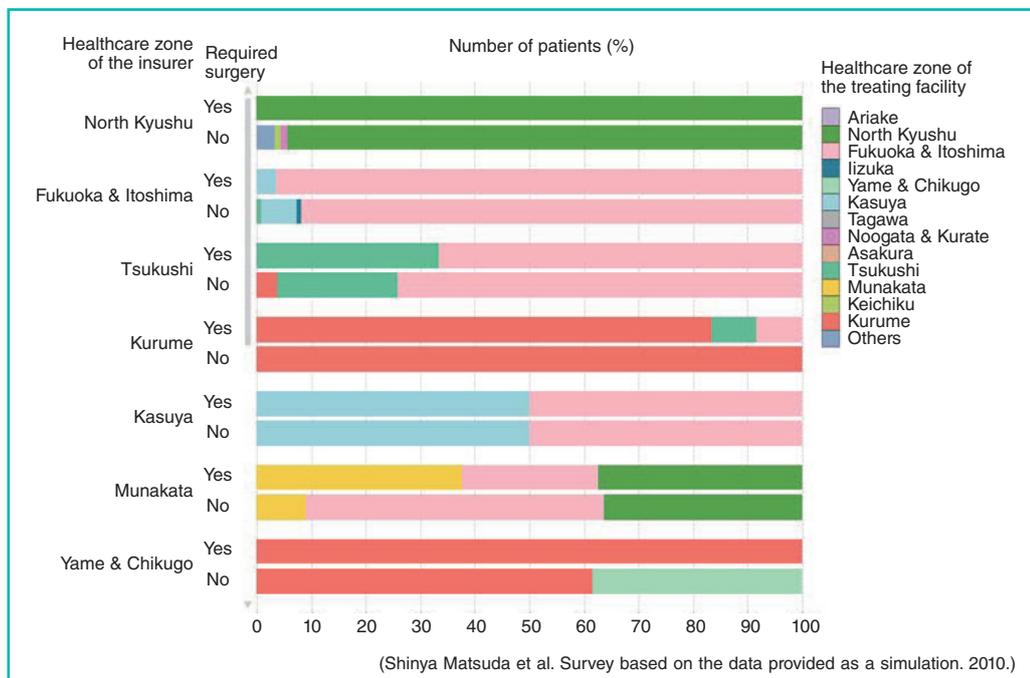
Fig. 12 Healthcare zones in which patients received care by the zones in which they reside
(Breast cancer; all ages; inpatients; national health insurance, Longevity Health Plan, and social welfare programs in total; shown in %)
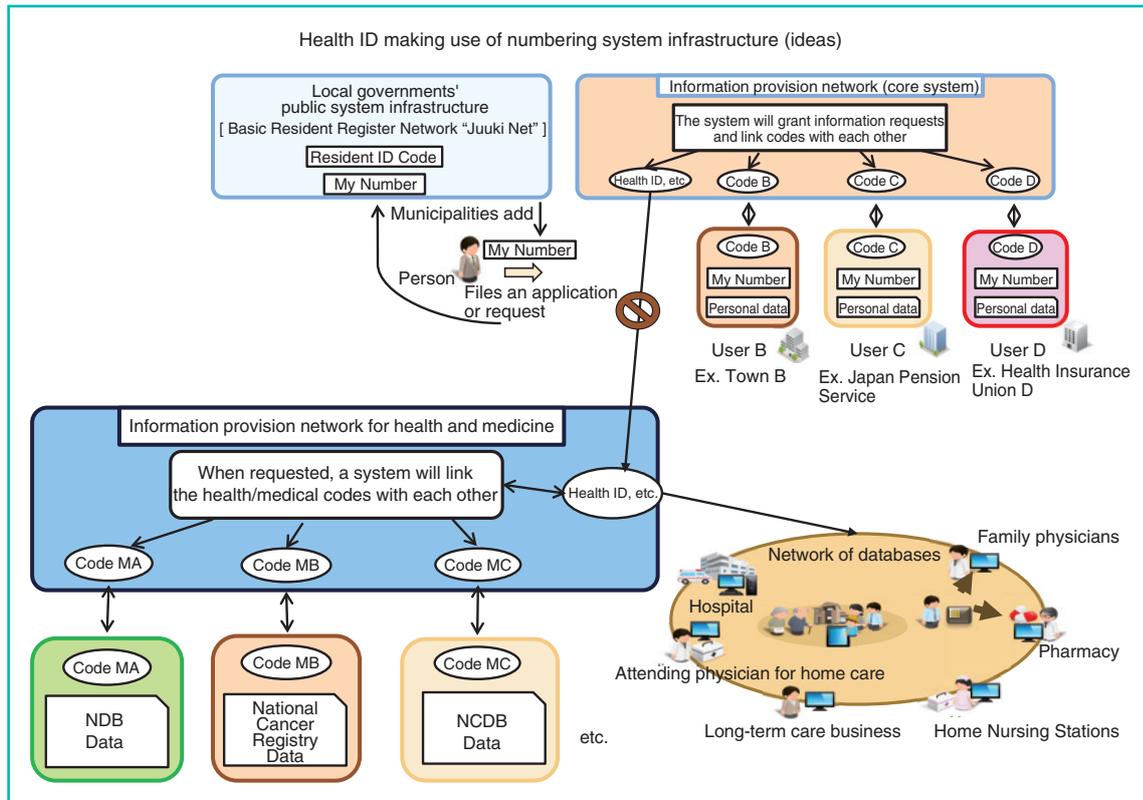
Fig. 13   Health ID making use of numbering system infrastructure (personal ideas)

System. The Taxpayer Identification Number System aims to understand individuals' income so that the burden of taxes and social security costs is shared equally among people. Legally speaking, it is not allowed to be used in healthcare practice or for in-kind benefits in nursing care.

On the other hand, those involved in healthcare liaison systems would have considerable trouble keeping track of each patient separately without the use of a numbering system. The Big Data that I have been talking about cannot be connected without a numbering system since each database is completely independent.

For example, there is a database on claims for nursing care insurance. However, claims for nursing care insurance and those for health insurance are completely unrelated currently, and there is no way to link them. They can be linked partly at the level of local governments, but not at the national level. Anyone would question whether healthcare issues could be properly addressed if things remain as such.

The Study Group on the Use of Numbering Systems in Healthcare and Other Fields prepared their interim report in December 2014, and suggested that the use of numbering systems should be promoted within the scope of current laws. In healthcare fields, for example, insurers should be allowed to use the numbering system. Moreover, the report suggests predetermining the specific occasions for linking information and reviewing the existing numbering systems and the nature of their numbers for further reevaluation.

Personal Opinion on the Use of Numbering Systems in Healthcare Fields

The upper half of **Fig. 13** shows the current numbering systems in the healthcare fields, but the rest is completely my personal ideas as to how these numbering systems could be better applied. Devising a system for ID numbering is surprisingly difficult, and there is no way we should not make use of the existing numbering systems. So,

I am starting with these numbering systems for healthcare ID numbering.

A single healthcare ID number will be created in a way that it cannot be easily traced back to the original data, so that the information linked with the other ID numbers of the same person cannot be easily connected. This healthcare ID will be used as needed in information networks such as collaborations between nursing care and medical care.

Patients have the freedom to choose, of course, so how his/her ID is used will be up to each patient. Meanwhile, codes reflecting various databases are prepared to be added to the healthcare ID as needed, such a code for the NDB or a code for the National Cancer Registry. This is the information provision network for health and medicine, and these codes are linked to each other only within this network.

It is therefore impossible to link these databases to each other in general. If someone filed a formal application of his/her plan, stating a reasonable cause to link the databases—a very important project for cancer management in Japan, for example—the matched data would be made available. That is what I picture the ideal system to be. Of course, we still have more to debate on this issue.

Act on the Protection of Personal Information and Big Data

Next, I would like to talk about the Act on the Protection of Personal Information. It is commonly understood that the current act is insufficient for addressing Big Data. The progress schedule of the government says that proper rules will be established sometime in 2015 (**Fig. 14**). Actually, there is no reason to prohibit the use of healthcare information in the first place.

Figure 15 shows the image of famous textbooks in medicine, which I also used when I was a student. Almost all of the knowledge in these textbooks comes from patient information; it does not come from test tubes or laboratory mice. So, the knowledge acquired from very sensitive medical records is written in these kind of textbooks. There is no way for medicine to advance if all this information is not available for use. Yes, it must be used.

That, however, does not mean that some patients or healthcare workers should be discriminated or suffer harm. For this reason, personal information protection and legislation for privacy protection began to develop all over the world from the late 1990s.

According to a report issued by the Academy of Medical Sciences in the United Kingdom in 2006, the data protection law was amended in 1998 and there are now rather strict requirements in healthcare and other fields.[1] The report, which is a book of over 200 pages, continues on to state that the amendment of the data protection law made medical research in the public interest very difficult to conduct, that financial demand for such research has increased, and that the privacy of patients is still not protected. The report also offers quite specific suggestions as to how these problems should be addressed.

Unlike the UK, Europe, or Japan, the United States has no comprehensive personal information law; however, the U.S. Department of Health & Human Services did enact the HIPAA[*6] Privacy Rule for patients' medical records. This privacy rule came into effect in 2003 for large medical institutions and then for all medical institutions in 2004. According to the 2009 Report by the Institute of Medicine, since the implementation of this privacy rule, epidemiological research has become very difficult or nearly impossible to conduct, or, when it is conducted, it is exceedingly expensive, and still patient privacy is not protected.[2]

So, it is a process of trial and error for any country to make a progress. Reports suggest that although rules are made, they have proven to be rather ineffective. Moreover, the use of data has become extremely difficult even when it is for fair use and there is no intention of infringing on anyone's privacy.

This is true for all countries, but privacy protection laws prioritize the protection of data and tend to be insensitive about the consequences of the decision to not use data. If no data were allowed to be used for writing the textbooks I mentioned, for example, progress of medicine would grind to a halt (**Fig. 16**).

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*6 HIPAA: Health Insurance Portability and Accountability Act.

Fiscal year	Short term			Medium term			Long term			KPI
	2013	2014	2015	2016	2017	2018	2019	2020	2021	

(1) Promote the creation of new business services by capitalizing on Big Data

(2) Promote the use of open data and Big Data

Prepare the environment for capitalizing on open data and Big Data (collaboration with the Council for Regulatory Reform) (incl. re-announcements)

- Installation of a new review board under the IT Strategic Headquarters [Cabinet Secretariat (CS)] (re-announcements)
- Review the personal information guidelines after clarifying the rules of personal data capitalization, and start working on the standardization of consent-obtaining procedures within the same year as early as possible [CS, Consumer Affairs Agency (CAA), & ministries and agencies in charge of guidelines for different business and practice areas] (re-announcements)
- Review the personal information guidelines based on the rules of personal data capitalization and implement standardization of consent-obtaining procedures [CS, CAA, & ministries and agencies in charge of guidelines for different business and practice areas] (re-announcements)
- Develop policies for revising the system, including adapting new legal measures [CS & relevant ministries and agencies] (re-announcements)
- Implement each measure according to the system revision policies [CS, relevant ministries and agencies] (re-announcements)
- Spread and promote efforts in the areas in which rules have already been established in advance [Ministry of Internal Affairs and Communications (MIC) & relevant ministries and agencies]

Promote data capitalization (incl. re-announcements)

- Support the creation of new industries [MIC & METI]
- Promote the capitalization of Big Data in each sector (urban planning, public transportation, disaster management, medicine, health, power companies, etc.) [relevant ministries and agencies] (re-announcements)

Develop human resources (re-announcements)

- Develop human resources that can capitalize on Big Data (e.g., data scientists) [Ministry of Education, Culture, Sports, Science and Technology (MEXT)] (re-announcement)

Develop technology

- Establish basic technology [MIC, MEXT, Ministry of Economy, Trade and Industry (METI)]
- Establish applied technology and international standardization [MIC, MEXT, METI]
- Practical application [MIC, MEXT, METI]

KPI:
- Review of system revision progress relating to personal data capitalization
- The total amount of new businesses and services created by Big Data capitalization

*KPI: Key Performance Index

(Source: IT Strategic Headquarters, 2013.)[3]

Fig. 14 Implementation Schedule (1. Creating new innovative industries and services and realizing a society that promotes the growth of all industries)

Medical knowledge is an accumulation of past experience, refined from a myriad of private, sensitive information.

Fig. 15 Examples of medical textbooks

Current Situation of and Challenges Regarding the Act on the Protection of Personal Information in Japan

Japan is unique in that the rules of the Act on the Protection of Personal Information that apply to different sectors—the private sector, independent administrative corporations, government administrations, or local municipal governments—actually vary. This is the so-called "2,000 problems"; there are 2,000 rules for personal information protection in Japan, and each is slightly different from the rest. You might think that a slight difference will not pose a

Act on the Protection of Personal Information
<Challenges>

> The Act pursues privacy protection but hardly addresses underutilization of data.

> The Act operates under different rules depending on the entity that acquires the information.

> Must not only protect information, but also provide practical and effective methods of preventing data abuse.

> The definition of *personal* information is vague, making it impossible to define what constitutes anonymization.

> We need an ID system that can be safely shared between the healthcare and long-term care service sectors.

Fig. 16 Challenges regarding the Act on the Protection of Personal Information in Japan

problem, but in reality, someone has to be responsible for following the rules within each institution (**Fig. 16**).

Healthcare liaison systems in particular require the exchange of highly private and sensitive information concerning patients' health and medical care across institutional boundaries. When exchanging information between institutions, for example, from a prefectural hospital to a private hospital or from a private hospital to a university hospital that is an independent administrative corporation, each institution has its own staff members in charge. So, each staff member in charge must file an application with the review committee for evaluation. If an independent administrative corporation, a national medical institution, a private hospital, a prefectural hospital, and a private clinic are launching a heal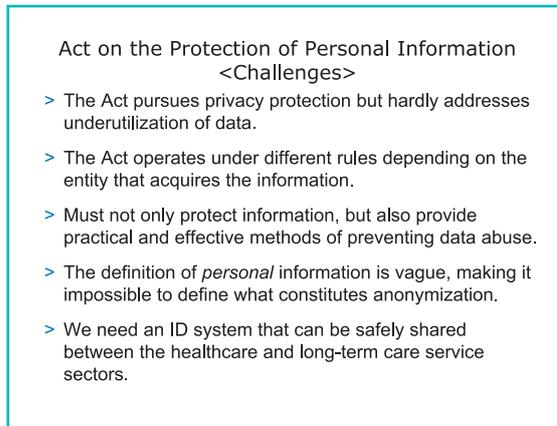thcare liaison project together, each of the 5 institutions has to apply and be approved; this is actually happening in reality. This is quite an impossible task for physicians in clinical practice, and it is becoming a major problem.

I should also point out that there is no effective measure against unjust use of information. There is a law against it, but it is quite difficult for this law alone to stop wrongful use of data with malicious intent in a practical sense.

Furthermore, the official definition of personal information, which commonly refers to any information with a distinct identity, is rather vague. To compare, there is no definition of what

exactly data safety is. The fact that there is no common ID is also a major problem because a person has no means to search for available information concerning his/her health or medical care. Therefore, the person cannot investigate whether that information has been used appropriately or whether it has been misused in any way.

When I said that there is no effective means of stopping unjust use, I am talking about the Unfair Competition Prevention Act as shown in **Fig. 17**. This is a law aimed at controlling industrial espionage.

There was a man in 2014 who was indicted for extracting a list of customer names from Benesse*[7]'s database and selling it to name list traders, and his charge was the violation of the Unfair Competition Prevention Act. It was not violation of the Act on the Protection of Personal Information. Apparently, the penalty for violating the Act on the Protection of Personal Information is not as significant as that of the Unfair Competition Prevention Act. That was the logic of the prosecution, but I feel somewhat questionable about his charge since I am not sure if what he stole constituted a business secret such as a blueprint for a new car.

Anyhow, my point is that imposing a penalty is quite difficult under the current legislation for personal information protection. I would seriously question whether the current system is capable of handling medical or health information appropriately.

Future Trends for Amending the Act on the Protection of Personal Information

Discussion on amending the Act on the Protection of Personal Information began in 2013, and soon the bill will be finalized and is expected to be submitted to the Diet during a regular session in 2015. The Japan Medical Association is holding a National Healthcare Information System Liaison Council meeting this coming Sunday, and I believe Mr. Uryu will be there as a presenter; nevertheless, the bill will soon be ready (**Fig. 18**).

The motivation for amending this law has actually come from the unsatisfied voices of the people involved on how it is difficult to capital-

*7 Benesse is a major correspondence education provider for children in Japan.

(From an Internet legal service)

Legally stipulating information larceny in the Penal Code is difficult because it is difficult to limit the methods of categorizing different types of information.

Is it true that stealing information is not a crime!? The reason that the Penal Code does not cover 'information larceny'

There is a regulation that punishes illegally obtaining information in the Unfair Competition Prevention Act. So, an industrial espionage can be punished. But what about others?

Is it really possible to determine the value of information only in terms of privacy? Is it possible to prevent discrimination from health and medical information (including genetic information)?

Perhaps we need an anti-discrimination law for physical/health information?

Fig. 17 Description of information larceny on a portal site for legal services

* Other nations including European countries and the USA are in the process of system revision, so it will likely take some time to ensure conformity with their efforts.
(Example: Proposed EU data protection rules, which the European Parliament is expected to adopt in the April 2014 Plenary Session)
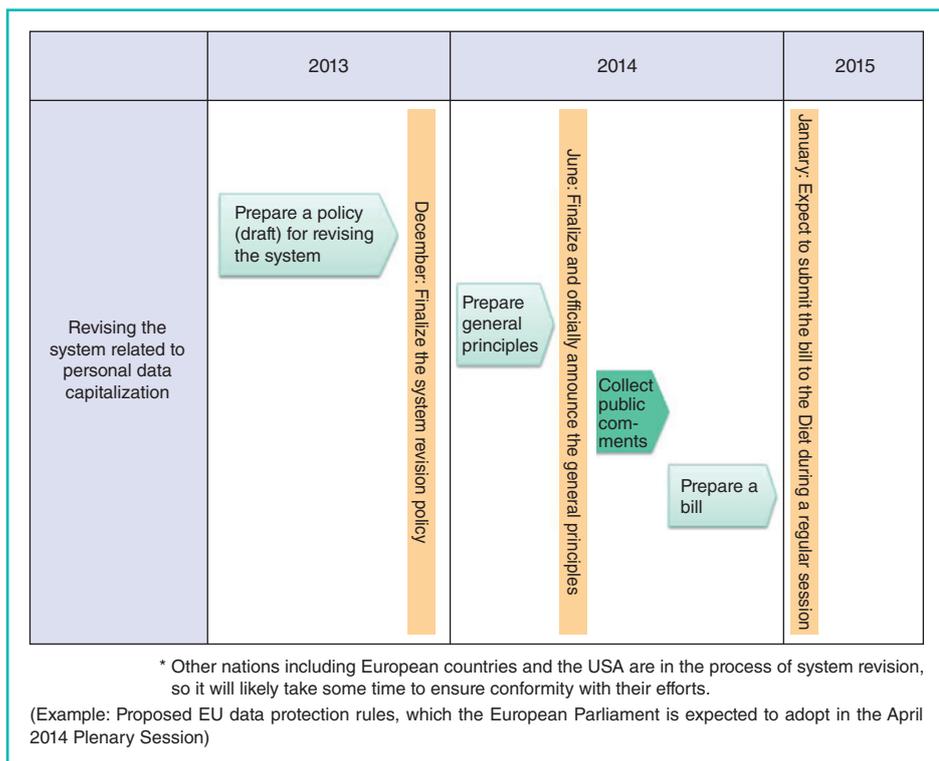
Fig. 18 Road map to revise the system related to personal data capitalization

ize on personal data in business or the current law is too strict in practice (**Fig. 19**).

The amendment thus aims to make it easier for people to use data. Presumably, the amendment is also meant to protect what must be protected. However, if we are not careful, there is a chance that we will end up simply relaxing the regulations and increasing the potential risk. I
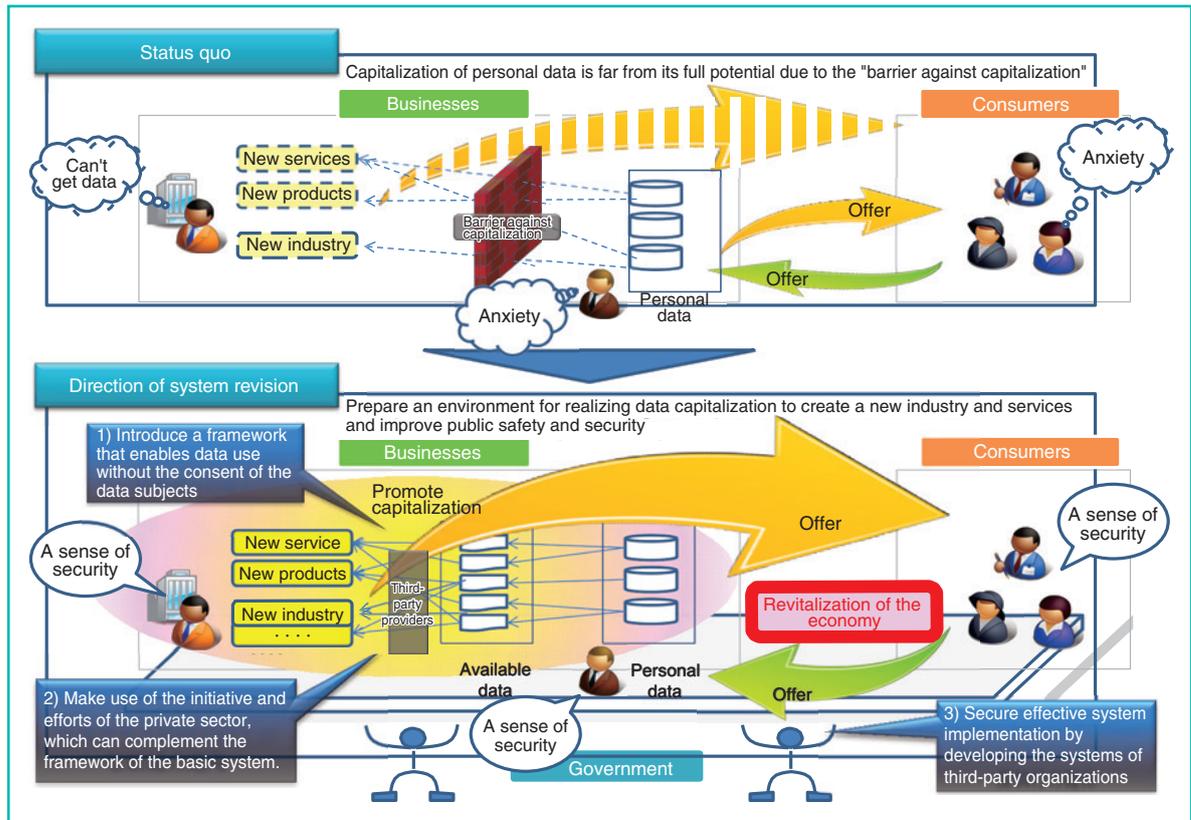
Fig. 19   Revising the system to capitalize on personal data

> Non-personal information
  - Information for which the source identity canNOT be **easily** identified even by cross-referencing external information
  - Equivalent of conventional non-connectible anonymized data and connectible anonymized data without corresponding tables -- but the meaning of **"easily"** is vague

> Personal information

  Personally identifiable information
  - Information for which the source identity can be "easily" identified

  De-identifying information (information with reduced specificity)
  - Information for which the source identity is NOT impossible to identify, but the risk is reduced to a certain extent.
  - Can be used without consent under certain conditions
    > Safety management → On-site Centers
    > No re-identification
    > No re-identification downstream as well

Fig. 20   Information derived from an individual

am afraid that I cannot go into specific details since the text of the bill is not finalized, which makes me a little irritated.

I can give you one example, nevertheless. The information derived from a person was considered either personal information or non-personal information before. In the bill, the personal information is further divided into 2 categories (**Fig. 20**).

One category refers to information from which an individual's identity can be easily identified, and the other category refers to informa-
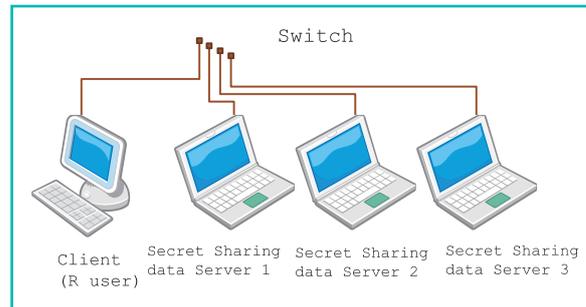
Fig. 21 Configuration diagram of a secure computation system

Fig. 22 Values are secretly shared

tion from which an identity cannot be easily identified but is not impossible. The latter is called de-identifying information.

The former is really personal information, so using it requires consent from the individual concerned—that has not changed. In the upcoming bill, the de-identifying information, on the other hand, can be used without consent if certain conditions are met. These certain conditions include that the data analysis has a proper purpose, that this purpose is clear, that the use of the data will not violate the rights of the individuals concerned, and that the safety and security of the data management is fully considered because the data can be analyzed or used by anyone if they are stolen. Moreover, the user must never attempt to re-identify the data. The draft version of the bill also stated that data processing will likely be entrusted to a third party

and that the safety and security of the data must be maintained by that third party as well.

There are other issues to consider besides these. What about using the data for non-intended purposes, for example? These questions need to be addressed carefully in the future.

Other Informatics Measures That Should Be Further Promoted

Finally, I would like to discuss what more can be done in terms of informatics measures. This work, called a secure computation, is something that my laboratory carried out (**Fig. 21**). A secure computation involves dividing the original data into 3 separate sets (**Fig. 22**). Once divided, each dataset turns into 3 columns of data. They carry no information value at all, and they are not encrypted but rather are truly divided, so there

Function	Description
sec.mean	Average
sec.var	Unbiased variance
sec.median	Median
sec.max	Maximum value
sec.min	Minimum value
sec.subset.eq	Filtering by a conditional expression (= equal to)
sec.subset.gt	Filtering by a conditional expression (> larger than)
sec.subset.ge	Filtering by a conditional expression (>= equal to or larger than)
sec.subset.lt	Filtering by a conditional expression (< less than)
sec.subset.le	Filtering by a conditional expression (<= equal to or less than)
sec.subset.ne	Filtering by a conditional expression (!= does not equal)
sec.shuffle	Randomly replace the order of records
sec.xtabs	Cross tabulate

Fig. 23   Various statistical functions available via secure computation

		Computation time	(Computation time: Breakdown)	
		[sec]	Secure computation	Others
Average		6.14	5.71	0.43
Median		82.30	81.88	0.43
Conditioning filter	(Dose 1) = 10	7.76	5.56	2.20
	(Dose 1) > 10	38.41	36.20	2.20
Cross tabulate	Main disease name	86.74	86.15	0.59
	Main disease name, Gender	172.66	171.81	0.85

Number of records in the target data: 50,001

Fig. 24   Processing times for various statistical calculations via secure computation

is no way to transform them back into the original data. It is still mathematically possible to carry out statistical calculations using such non-transferable data. This method allows us to compute the total healthcare expenditure or total dose used for a given drug in a situation where no patient case can be seen.

For example, there are diseases for which very few cases exist and yet they have a significant social impact. Let us assume for now that the Ebola hemorrhagic fever arrived in Japan, and 10 patients presented with it. The media would desperately cover the news, and the identities of those 10 people would be revealed eventually. If someone tried to use or analyze the Ebola patients' data, they could easily identify who those patients were from just the data. If a

researcher wanted to know the total dose of a drug and the patients' prognosis, this method of secure computation would enable such an analysis without actually seeing the original data.

We implemented secure computing method as the functions of common statistical language "R," and functions implemented are shown in **Fig. 23**. We can perform these kinds of searches and compute various statistical values, including the mean, unbiased variance, median, and maximum and minimum values. I believe most statistical procedures are feasible.

As for the computation speed, it is true that it takes longer when compared to the original, non-processed data. It may take 10 times longer or more, but one can muddle through in less than 100 times as long (**Fig. 24**).

There are other procedures similar to secure computation, too. It is actually a very hot topic of study right now. For example, it should be possible to trace back the original identity of certain data without actually looking at the data. It is theoretically possible, and is called secure traceability. In fact, my colleagues and I are in the process of bringing 3 or 4 organizations together to work on a project to study secure traceability on a continuous basis now.

I am afraid that my talk may have become slightly incoherent. I would like to thank the audience for their attention.

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Medical Big Data for Research Use: Current Status and Related Issues[*1]

Koichi Benjamin ISHIKAWA[1]

Abstract

Advances in the computerization of information and development of technology have mitigated restrictions on handling of a large amount of information. This has resulted in growth of expectations for the use of large-scale databases, or so-called "big data." This is also the case in the field of healthcare. Projects that involve building of the national receipt database (NDB) of medical fee bill (receipt) information and special health check-up information based on the Act on Assurance of Medical Care for Elderly People and the development of medical information databases have been pursued by the national government, and considerable attention has also been focused on researches conducted through the secondary uses of publicly collected data.

Aside from these trends, there are numerous projects which collect diagnosis procedure combination (DPC) data to build large-scale databases for research purposes. Following to the ethics guidelines for epidemiologic studies, they collect and analyze anonymized DPC data from cooperating institutions.

This communication concentrates on the use of DPC data, and outlines the scale of data currently available for research use. Examples on the use of DPC data will be shown for analysis on the current status of clinical practice from the microscopic perspective and macroscopic analysis of community medical care provision. Additionally, potential for extending studies to long-term outcomes research, limitations and issues related to the use of medical big data will also be discussed.

Key words Large-scale medical databases, DPC data, Open data, Clinical processes, Community care provision

Usage of Big Data in the Medical Field

This presentation will describe the use of big data for research, including current applications and future expectations and needs. The focuses will be placed on the collection and processing of big data related to provision of clinical services, conducted by the national government, or within epidemiologic studies. The use of data in the private sector and other types of data such as genomic and lifestyle data should be left to a different occasion because uses of such data are still limited.

Building of Databases Promoted by the National Government

As mentioned by Dr. Ryuichi Yamamoto, the government's efforts to build large-scale databases in the field of healthcare have progressed tremendously. The government is collecting data under relevant laws such as the acts on assurance of medical care for the elderly and nursing care for the elderly, as shown in the left portion of **Fig. 1**. In addition, the national cancer registry is scheduled to launch in January of 2016, according to the Act on Promoting Cancer Registries.
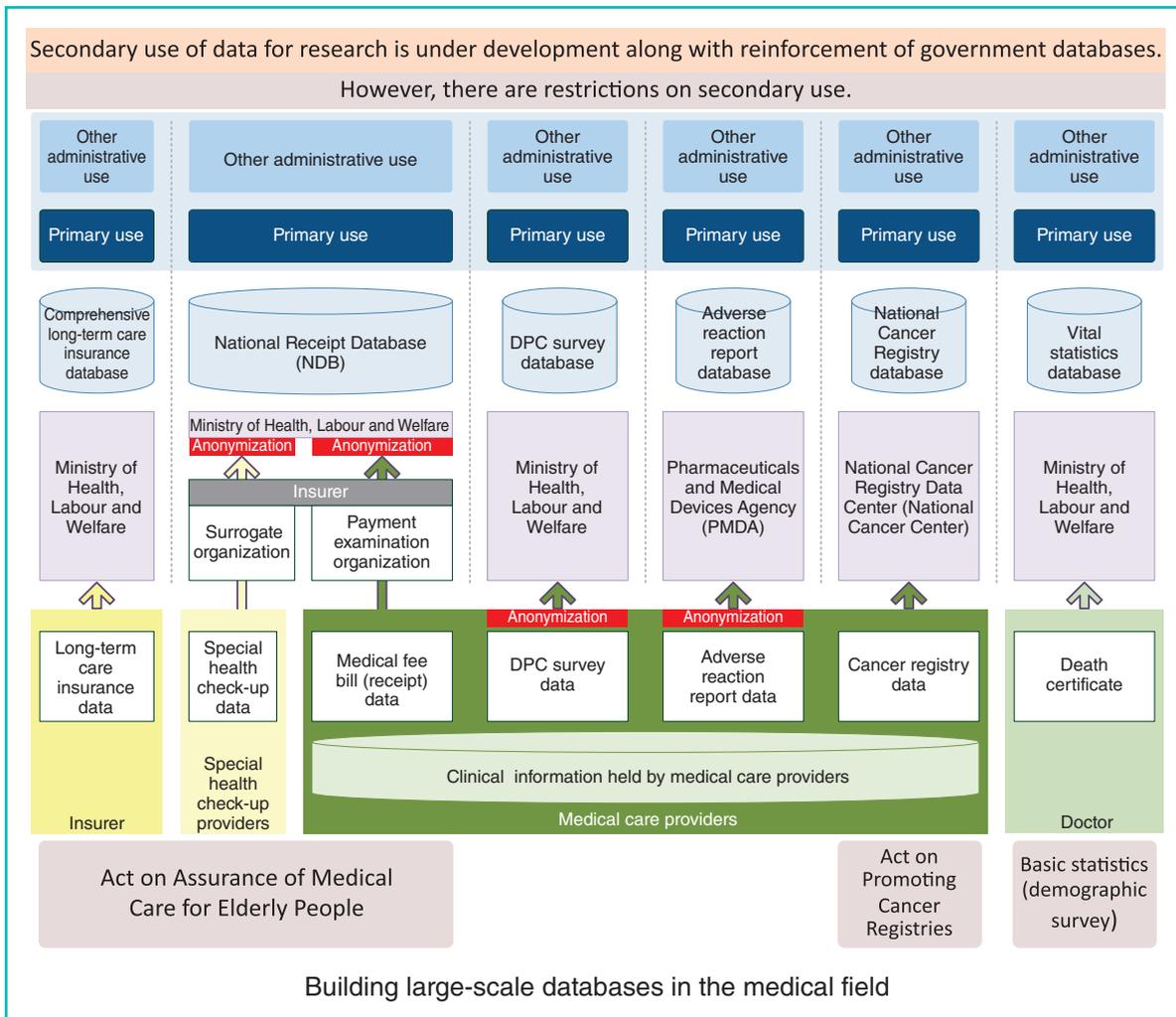
Fig. 1   Medical databases promoted by the Japanese government

Demographic data is collected to serve as the nation's core statistics.

To illustrate some examples, under the Act on Assurance of Medical Care for Elderly People, data on long-term care insurance are submitted by each local government to the Ministry of Health, Labour and Welfare (MHLW), forming a database for Health and Welfare Services for the Elderly. As for the national receipt database (NDB), medical fee bill (medical fee receipt) data are first submitted by each medical care provider to a payment examination organization. The MHLW then collects such data, anonymizes them, and forms the database. In the same manner, data on special health check-ups are obtained from providers and are sent to insurers via surrogate organizations. They are then sub-

mitted to the MHLW, where they are anonymized to form databases. The data, once compiled into databases, can be used in various ways.

In this array of databases, there is a new project of the National Cancer Registry. The National Cancer Center is in charge of the data management under commission from the government. Data on cancer cases, at the time of occurrence, newly found in hospitals and clinics with beds are compiled into the National Cancer Registry database, and used for reporting on cancer incidence and outcomes.

Current Status of the Use of Medical Databases

Within this framework, there is another trend,
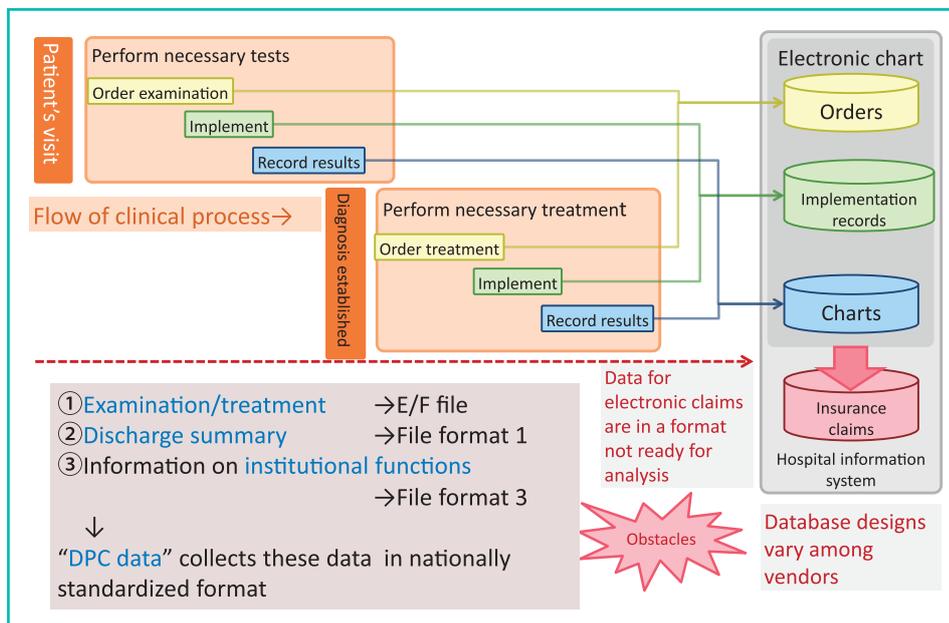
Fig. 2   Flow of clinical process and data

i.e., collection of data not directly prescribed by law. One example is the diagnosis procedure combination (DPC) survey. Anonymized data are collected from medical institutions by the MHLW, as part of an information gathering process conducted under the Health Insurance Law. In a sense, this is similar to conducting studies. The MHLW uses these data as source materials for revision of DPC classifications and price setting. For the purpose of collecting information on adverse drug reactions, the adverse drug reactions observed at the scene of clinical practice are submitted to form a database, and the data is used for various usages including revision of the package inserts.

Recently, the private sector, healthcare related industry, and researchers are requesting to use such databases, so the government is experimenting in secondary data use of public data. However, as Dr. Ryuichi Yamamoto mentioned in his lecture, in reality, there are many restrictions on the secondary use of data.

Relationships between Medical Services and Data

Patients who visit medical institutions undergo necessary examinations according to physicians' orders; healthcare professionals working in various specialties perform examinations under these orders. The results of the examinations, such as direct outputs from medical apparatuses, diagnostic imaging and reports or diagnosis based on such data are then recorded in patient charts. Thus, medical information is obtained through 3 steps comprising orders, implementation records and results (**Fig. 2**).

After this examination phase, a diagnosis is established, and a treatment plan is then devised according to the algorithm or guidelines for the diagnosis. Next, the physician in charge gives instructions pertaining to the treatment, and the results are recorded after implementation of the treatment.

This flow of information is captured by hospital information systems (HIS). Physicians' orders are recorded and collected in an order-entry database, data from each process performed under physicians' orders are recorded as implementation records, and the results and summaries are recorded in medical charts.

The HIS have been very actively developed in Japan since the 1980s. Electronic recording of physician order entry became available in almost every hospital during the last century. In large-scale hospitals, supporting systems were developed to manage the ongoing process of examinations and treatments because these tasks were monumental. Later, development of electronic medical charts was started, and a consid-

erable number of medical institutions had obtained such databases by the beginning of this century.

Medical institutions are required to charge and collect medical treatment fees. So they sent charge data to payers, based on the data stored in the three databases.

Obstacles to Secondary Use of HIS Data

Although in-hospital systems were functioning efficiently, there were barriers to the secondary use of these data.

For instance, the structures of the databases varied according to the vendor (company) that had developed the hospital information system. Even when the databases of hospital A and hospital B were developed by the same vendor, the databases were often incompatible due to the differences in versions of the product.

Sometimes, the code for recording a service in hospital A may differ from that in hospital B, bearing obstacles to compare the data from two hospitals. To solve such issues, standardized codes for electronic processing of medical fee bills were developed and efforts were made to promote the use of such codes.

Even when above issues were resolved, the data format for electronic claims was not suitable for analysis. They were recorded in a way mimicking paper claims and careful processing was needed to transform them to tabular data. This problem persisted for a very long time, until DPC data format was made available.

DPC Data Collected in Nationally Standardized Format

The core concept of DPC data is the submission data in an itemized list format. Required items in the medical fee bill, such as tests and procedures performed, drugs administered are exported as a list from in-hospital database. This format is referred to as E/F files, recording information on when, where, and to whom a certain examination (e.g., x-ray examination) or a certain drug at a certain dose is provided.

In DPC-based reimbursement system, information about the diagnosis and treatment of patients is needed to classify patients into case mix. To collect these data, discharge summaries carrying patients' basic demographics, diagnosis and other items in a standardized manner are recorded in file format 1.

It is also important to evaluate the functions of each medical institution in the DPC system. Relevant data on institutional functions and organizational structure is collected in file format 3. Using these standardized formats, data have been collected since 2006.

Reasons for Producing DPC Data

The DPC data is primarily produced to gather information for the prospective payment system for acute-phase inpatient hospital care [DPC/per-diem payment system (DPC/PDPS)] (**Fig. 3**).

The DPC/PDPS system is basically comprised of two technologies: grouping of patients by DPC, and bundled payment per day according to DPC classification.

However, another important technology in DPC/PDPS is the DPC data. They were produced in more than 1,800 hospitals in 2014. Although they are only prepared by about a quarter of general hospitals nationwide, their coverage of general hospital beds now exceeds 60% and they cover 70% of discharges, i.e., 10 million of 15 million discharges per year.

Currently, DPC/PDPS prospective payment system is only applied to acute inpatient care, but inpatient care is not independent from outpatient care. The MHLW research group on DPC/PDPS began to collect outpatient care data in E/F files since 2006. Afterwards, the MHLW started to do so since 2012. This makes the DPC data format a de facto standard for collection of clinical information in both inpatient and outpatient settings.

Information Collection through DPC Data

The basic reason for the DPC data format to spread across the nation to present level is that submitting data was required for claiming medical fees by DPC/PDPS. However, starting this year, not only DPC-paid hospitals but all facilities that claim basic inpatient care charges with higher nursing standards (7-nurses-per-patient nursing) are required submit inpatient and outpatient DPC data. Also, hospitals with regional comprehensive care wards (i.e., hospital wards
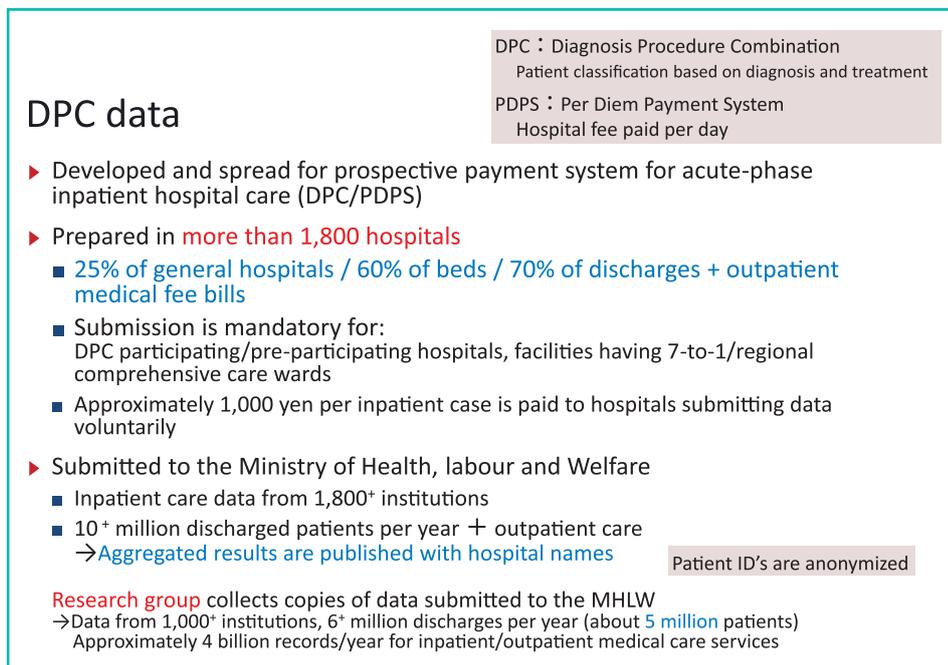
Fig. 3   DPC data

that accept patients in need for medical care after the acute phase and provide support to return to their homes or to nursing facilities), are required to submit DPC data.

In addition to these hospitals that are obliged due to claiming special inpatient services, other hospitals can receive 1,000 yen per admission if they submit DPC data voluntarily. For such reasons submission of DPC data has grown to a level previously mentioned.

It should be noted again that DPC data are anonymized at the time of submission from medical institutions. The MHLW collects these data and analyzes them according to the medical institution code. The results of analysis are published together with the names of hospitals to provide reference information for evaluation of hospitals within the DPC system. They are made available to the public as an open data and consumers can see which hospitals are participating in DPC/PDPS and how they provide care.

Big Data Usable for Multiple Purposes

DPC data are not solely used by the MHLW, but are also used by hospitals for administrative and other purposes. They can analyze DPC data either internally or with support from third-party

organizations such as consulting companies. At the same time, there is a research project funded by the MHLW Grants-in-Aid for Scientific Research that collects DPC data from hospitals. The research group has a long history starting from introductory phase of DPC/PDPS.

Currently the research is led by Professor Kiyohide Fushimi of Tokyo Medical and Dental University. Participating researchers like myself work under his supervision. Out of 1,800 hospitals that submit DPC data to the MHLW, two-thirds, about 1,000 hospitals provide copies of the data to our research group. The data currently holds more than 6 million discharged cases for 5 million anonymized patients per year.

Detailed data for inpatient and outpatient clinical services (what treatment was given to which patient, on which date, and in which hospital) sums up to 4 billion records per year. In recent years, these data have become available all year round. In our research group, the data is available since 2010.

These data are not collected pursuant to the law or as part of the government project. Data are collected for research after obtaining approval from the ethics board of research organization. The study complies with the personal information protection policy for research and

DPC data

Analysis from microscopic perspective

▶ Analysis on cancer chemotherapy (2012 research group data)
- Patients on chemotherapy ： 833,000 persons
- Patients admitted: 367,000 persons / total discharges ： 626,000
  ▶ Reference: deaths at the time of discharge: 42,400
  →16.2% of all deaths at discharge / 5.09% of patients admitted for chemotherapy
  ↓
- Lung cancer (040040)
  Patients admitted for chemotherapy: 45,100 / total discharges: 99,800
  ↓
- Treatment with carboplatin + paclitaxel (regimen)
  →No. of patients: 4,834 / No. of discharges: 7,584 / 564 institutions

Fig. 4   Analysis from microscopic perspective using DPC data

the protection of trial subjects stated in the Declaration of Helsinki. As the research does not involve medical interventions, and uses only anonymized retrospective data, the study protocol is devised according to the ethics policy for epidemiologic research. For researchers, a large standardized data at reasonably low cost is already available for analysis.

So let me show you some findings from the research group.

Analysis from the Microscopic Perspective

Here, I will show you an example from microscopic perspective (**Fig. 4**).

Because I work at the National Cancer Center, I have been in charge of analyzing data on chemotherapy for cancer in our research group.

In 2012, the research group had data on approximately 6 million inpatient care cases or 5 million inpatients. Including outpatient data, the number of unique identifications (IDs) reached tens of millions. Using that data, we identified 830,000 patients who received chemotherapy related drugs at either inpatient or outpatient settings. The diagnosis or the site of cancer was not available for outpatients, but for 360,000 inpatients diagnosis with ICD-10 codes were available. We linked 630,000 admission and outpatient records to the 360,000 inpatients for analysis.

We found about 42,000 deaths for cancer chemotherapy patients over 12-month period. These deaths account for about 16% of all

deaths observed in DPC data used by our research group. About 5% of patients who have undergone chemotherapy had died.

Analysis by Disease Name Is Feasible

With DPC data we can not only tabulate patients by chemotherapeutic agents but also by diagnosis. Among the 360,000 patients, 45,000 were lung cancer patients. The total number of admission was nearly 100,000. There, we can see how the hospitals provided chemotherapy.

The results of this type of analysis have been published or reported since 2007. Two-drug chemotherapy using carboplatin and paclitaxel is common in the treatment of lung cancer, and 4,800 patients, corresponding to a little more than 10% of the 45,000 patients with lung cancer, receives this regimen. They had 7,500 admissions in a year and 564 hospitals provided the therapy.

Although knowing the chemotherapy regimen by diagnosis is in itself very informative and important, specific analysis of the E/F files of these patients provides the following useful information.

Figure 5 shows the data from patients with lung cancer (040040) who underwent two-drug chemotherapy with carboplatin and paclitaxel. It is a complex graph, and it may be difficult to find the point most worth paying attention to, but attention should first be focused on the light blue, orange, and gray bars. This bar graph has the length of stay on the horizontal axis and the
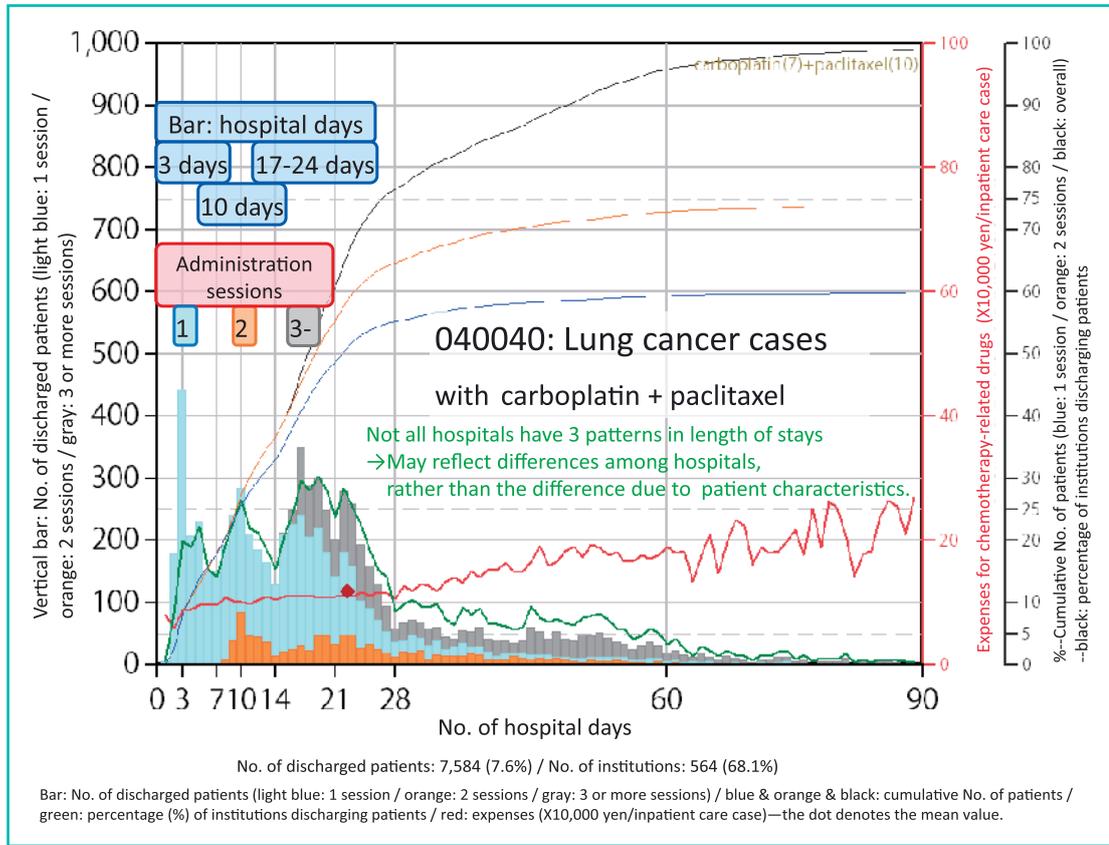
Fig. 5　Lung cancer chemotherapy admission (treated with carboplatin and paclitaxel)

number of patients on the vertical axis.

As is clear from the graph, a hospital stay of 3 days and 2 nights was most common among approximately 7,000 inpatient cases. There were nearly 400 patients. But we can see a peak in length of stay at 10 days and another at 17-24 days, showing a total of 3 peaks.

Therapeutic Processes in Medical Care as a Whole Can Be Understood

Many anticancer drugs are not continuously administered for many days. The standard method of administering this chemotherapy relies on giving the drugs in a cycle of 1 or 3 weeks.

Let us pay attention to the number of administrations of anticancer drugs during a hospitalization. The light blue part of the bar graph denotes patients who received only one session per hospitalization, whereas the orange and gray parts denote those who underwent 2 sessions and 3 sessions, respectively. For example, the orange part at 10 days shows patients who had

the first session and spent a week in the hospital and were discharged after the second session. For patients in gray part, they received 3 sessions of one-week-cycle chemotherapy. But for light blue bars representing a considerable number of patients, they received only 1 session of chemotherapy in an admission.

The necessary length of stay usually varies according to the patient's disease condition. However, these 3 patterns in length of stay were not necessarily found in all hospitals. Let us pay attention to the green line in **Fig. 5** that denotes the percentage of hospitals with patient discharged at specific length of stay. There is a scale of 0-100 on the right side. On this scale, the peak percentage of hospitals reaches only up to about 30% regardless of length of stay.

If majority of hospitals had 3 peaks, it may be reasonable to assume that hospitals choose the length of stay according to the patients' conditions. However, under the situation that each peak reaches only 30%, it seems to indicate that three patterns are inherent to the practice pat-

terns of treatment at each hospital, rather than being attributable to the characteristics of the patients.

This is an analysis that yielded outstanding results. But please be relieved to know that therapeutic strategies do not differ to this extent for other types of cancer or regimens among hospitals. Even in cases with lung cancer, regimens using other drugs are more standardized. For women with uterine cancer or ovarian cancer, the same combination of drugs, carboplatin and paclitaxel are more standardized; a hospital stay of 3 days and 2 nights is adopted in more than 50% of hospitals.

Analysis of DPC data shows which practice patterns are currently common and how much variability exists between hospitals. It gives guidance on what kind of care we can guarantee for patients in Japan, and that had not been cleared up to now. These features will be visible through the use of medical big data.

Analysis from the Macroscopic Perspective

Then what can we see from the macroscopic perspective, if we use DPC data (**Fig. 6**).

We have seen difference in patterns of care, and let us turn to see how care is provided from a wider perspective.

In DPC survey data, 7-digit postal code for the patient address was included as an item in file format 1, which holds discharge summaries. If we can map the 7-digit postal codes on a map with latitude and longitude, we will be able to know from where patients are coming. In addition, if we can see which hospital patients are admitted to, we will be able to know which hospital is responsible for the community and what role they play.

As a pioneering example of such analysis, Dr. Yamamoto presented the findings by Professor Shinya Matsuda, from an analysis of NDB data describing a cross-section of location of patients (or payers) and location of hospitals. With DPC data processed properly, we can do more detailed analysis like I show you next.

Discharge summaries recorded in file format 1 include information on whether or not a patient was transferred by ambulance on admission. Extracting acute myocardial infarction (AMI) patients transferred by ambulance and plotting them would produce a map shown in
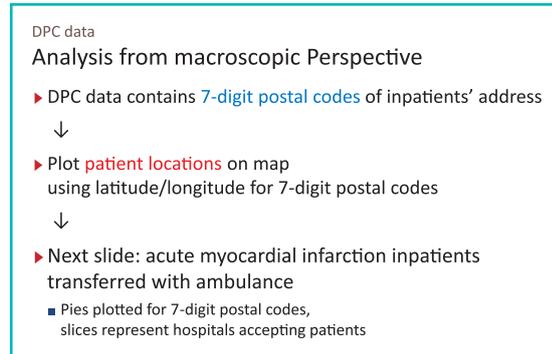
Fig. 6 Analysis from macroscopic perspective using DPC data

Fig. 7.

In order to protect the privacy of patients following ethics guidelines, and to adhere to the data use agreements of participating hospitals, background map is not shown on **Fig. 7**. It shows relative positions of the 7-digit postal codes, and color represents hospitals accepting patients.

On the upper right side of the figure, there are 2 medical institutions shown in dark and pale pink that cover a region. For other regions, dense plots of postal codes reflect area with high population density. In such areas, there are multiple hospitals to which patients are admitted to. It shows that geography divides hospitals market. In urban areas hospitals as a group is responsible for care for AMI in a region.

These are the results from analysis of DPC data, from microscopic and macroscopic perspective.

Strengths of DPC Data

Using DPC data, which constitute an example of medical big data, analysis on clinical care processes will provide statistics on hospital care by DPC (patient category) or by provider (hospitals). It is possible to see the length of stay for chemotherapy admissions using particular drugs, allowing comparisons among different medical institutions (**Fig. 8**).

There is an analysis by members of our research group, comparing conventional and laparoscopic surgery that found peculiar difference in the percentage of patients who required blood transfusion and the actual transfusion volume required. Because DPC data records clinical tests or interventions with the computerized

Acute myocardial infarction / ambulance transfer

7-digit postal codes of patients' address
(Background map is not shown
according to the terms of data use)
   Color: Hospitals accepting patients
   Size: Number of cases
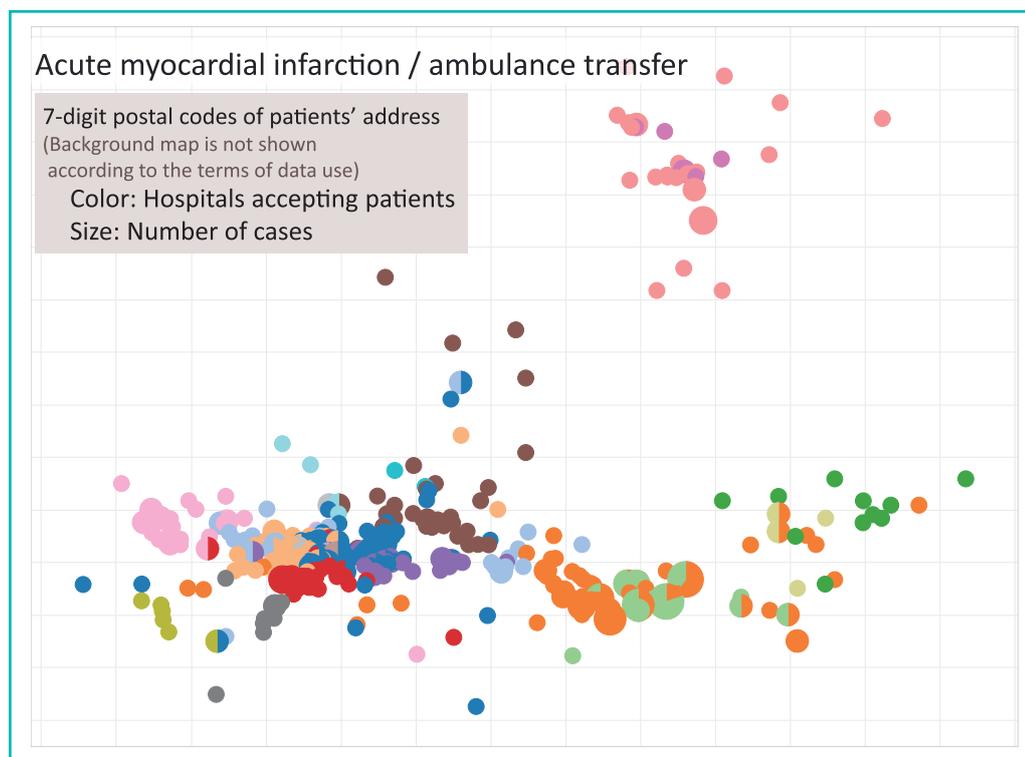
Fig. 7   Map of acute myocardial infarction patient address by accepting hospital

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Strengths of DPC data

▶ Analysis on clinical care process

- ■ Aggregated statistics by DPC classification, by hospital
  - ■ Data for each DPC classification: length of stay (overall/before surgery/after surgery), charges for procedure, medication, devices etc.
  - ■ Comparisons among hospitals
  - ■ Analysis on drugs used (chemotherapy, etc.), types of surgical procedures
- ■ Analysis on detailed care patterns
  - ▶ Variance in services performed during inpatient stay
  - ▶ Comparative analysis, such as laparotomy vs. laparoscopic surgery
- ■ However, there are limitations due to granularity of records in fee-for-service billing data
  - ▶ Site and projection of CT/MRI, distinction between CT/MRI scans is limited to first session in month

▶ Analysis on hospital functions and patient catchment area

- ■ Using 7-digit postal codes for patient address, recorded in file format 1
- ■ Open data published by the Ministry of Health, labour and Welfare as results from DPC survey

Fig. 8   Strength of DPC data

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code for reimbursement, there are limitations for analysis at a detailed level.

With regard to diagnostic imaging tests, patients with lung cancer initially undergo CT examination to determine the tumor size, and then brain and/or liver may be examined for
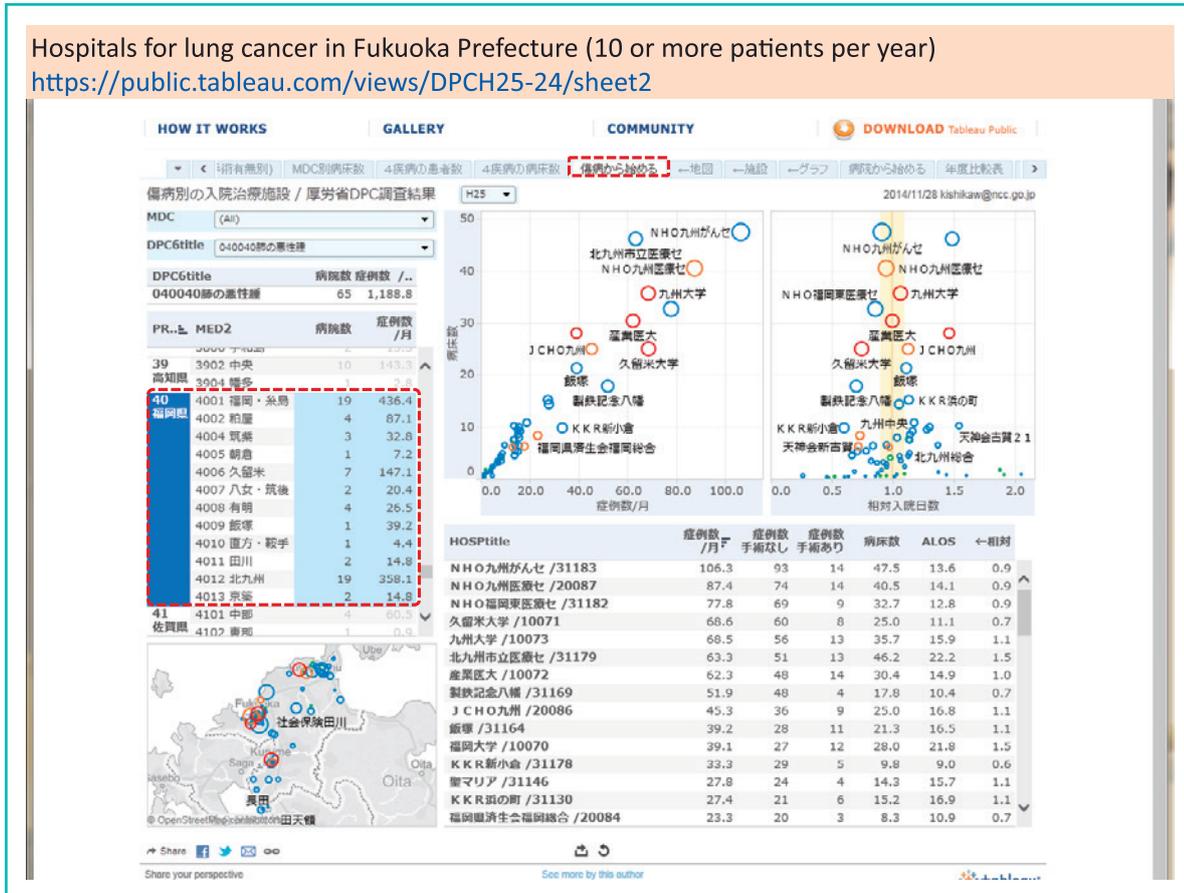
Fig. 9 DPC survey results by the MHLW (2013): Hospitals for lung cancer inpatient care in Fukuoka Prefecture

metastasis if they are suspected. For such occasions, DPC data allows us to analyze the number of examination. However, the site of interest for a CT examination is not recorded in the current format of the medical fee bill or items covered by DPC data. So there is a limitation in studies only using DPC data.

Analysis of DPC Data at a Higher Level

DPC data also allows us to analyze the functions of hospitals within a geographical area. If raw data were available, we can obtain maps like **Fig. 7**. More advanced analysis will be possible, if we use the results of DPC survey published by the MHLW.

The DPC survey results are available from the MHLW website. Published data include list of participating hospitals for the survey, distributions of patients by gender and age group by

DPC patient classification, chemotherapeutic regimens and drug combinations used, and so on. In addition, detailed data for participating hospitals are also available concerning the type of treatment, number of treated cases, and type of disease by diagnosis or by major diagnosis category.

For instance, **Fig. 9** shows the results for lung cancer admissions. The table in the lower right panel of the figure shows the list of hospitals in Fukuoka prefecture, ranked by the number of treated cases per month. If we focus on the number of hospitals, we see that there are many hospitals for lung cancer in this prefecture.

In Fukuoka Prefecture, there are 62 institutions with 10 or more lung cancer discharges per year. **Figure 10** is a map produced by plotting each hospital on it, and coloring according to the time required for residents to reach the nearest hospital.

Fig. 10   Lung cancer inpatient care coverage

1. Shimonoseki; 2. Ube/Onoda; 3. Yamaguchi/Hofu; 4. Shunan; 5. Yamaguchi Prefecture; 6. Kitakyushu; 7. Munakata; 8. Nogata/Kurate; 9. Tagawa; 10. Keichiku; 11. Iizuka; 12. Kasuya; 13. Fukuoka/Itojima; 14. Chikushi; 15. Fukuoka Prefecture; 16. Asakura; 17. Kurume; 18. Yame/Chikugo; 19. Ariake; 20. Kumamoto Prefecture; 21. Kamoto; 22. Kikuchi; 23. Aso; 24. Western area; 25. Oita Prefecture; 26. Northern area; 27. Eastern area; 28. Central area; 29. Hohi; 30. Saga Prefecture; 31. Southern area; 32. Sasebo; 33. Northern area; 34. Central area; 35. Nagasaki; 36. Nagasaki Prefecture

If we sum up the population by driving time, 70% in the prefecture can be admitted to a hospital within 15-minute range. If patients may travel up to 30 minutes, the coverage of the population rises to 96%. We can use microscopic DPC data in a macroscopic analysis to see what can be done in local areas and how it impacts the population.

For lung cancer, the population coverage is high, and we may satisfy with the level of care provision in Fukuoka. On the other hand, for uterine cancer, there are only 26 institutions with 10 or more discharges per year (**Fig. 11**). In this case, people who can receive inpatient care for uterine cancer in a local hospital within 15 min-

ute drive account for little less than 50% of the population. A quarter of patients may drive to an adjacent town for 30 minutes to be treated, but the remaining quarter of prefecture has to drive over 30minutes. That is a remarkable difference from lung cancer, and it is evident that accessibility to inpatient care differs by types of cancer.

Weakness of DPC Data

Today, we saw the strengths of DPC data with examples from microscopic and macroscopic analyses. However, there are research areas not suitable for DPC data (**Fig. 12**). For instance,
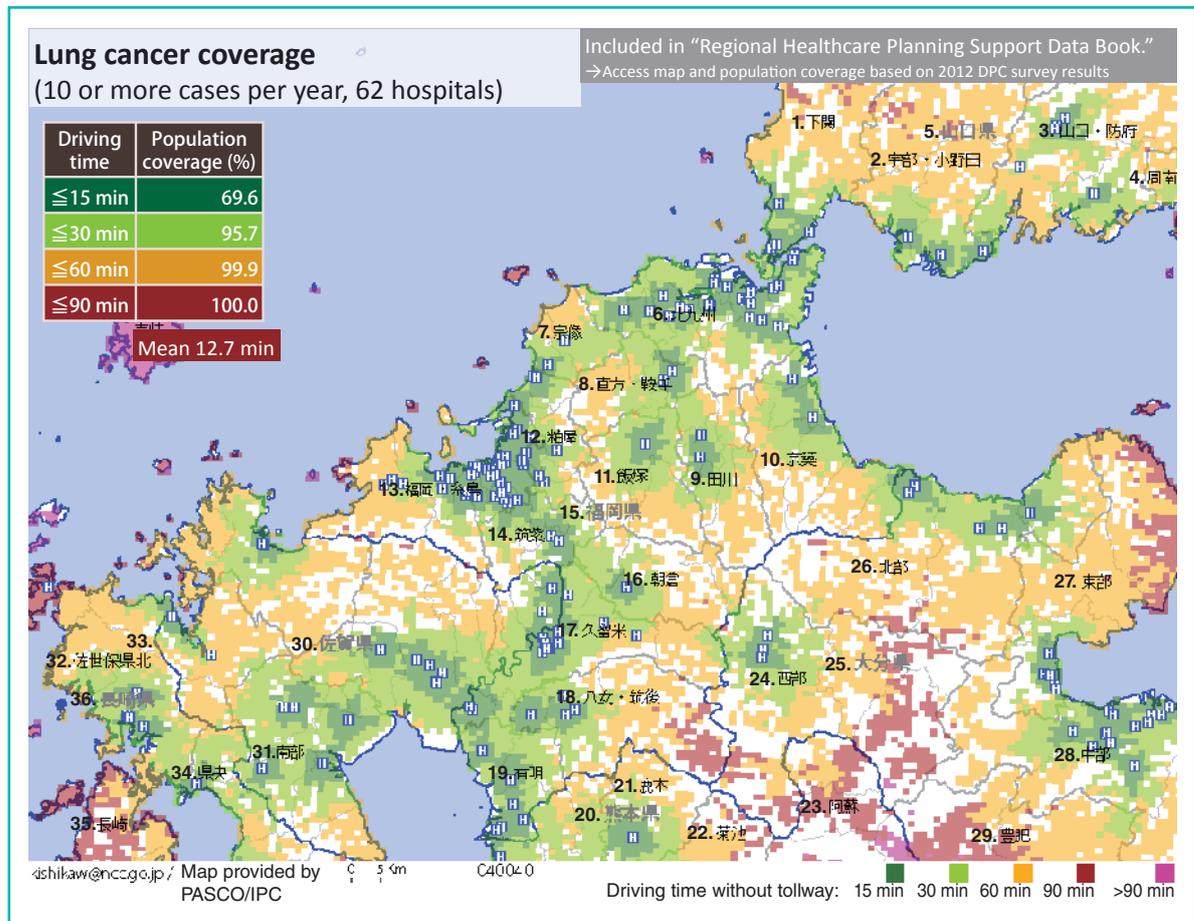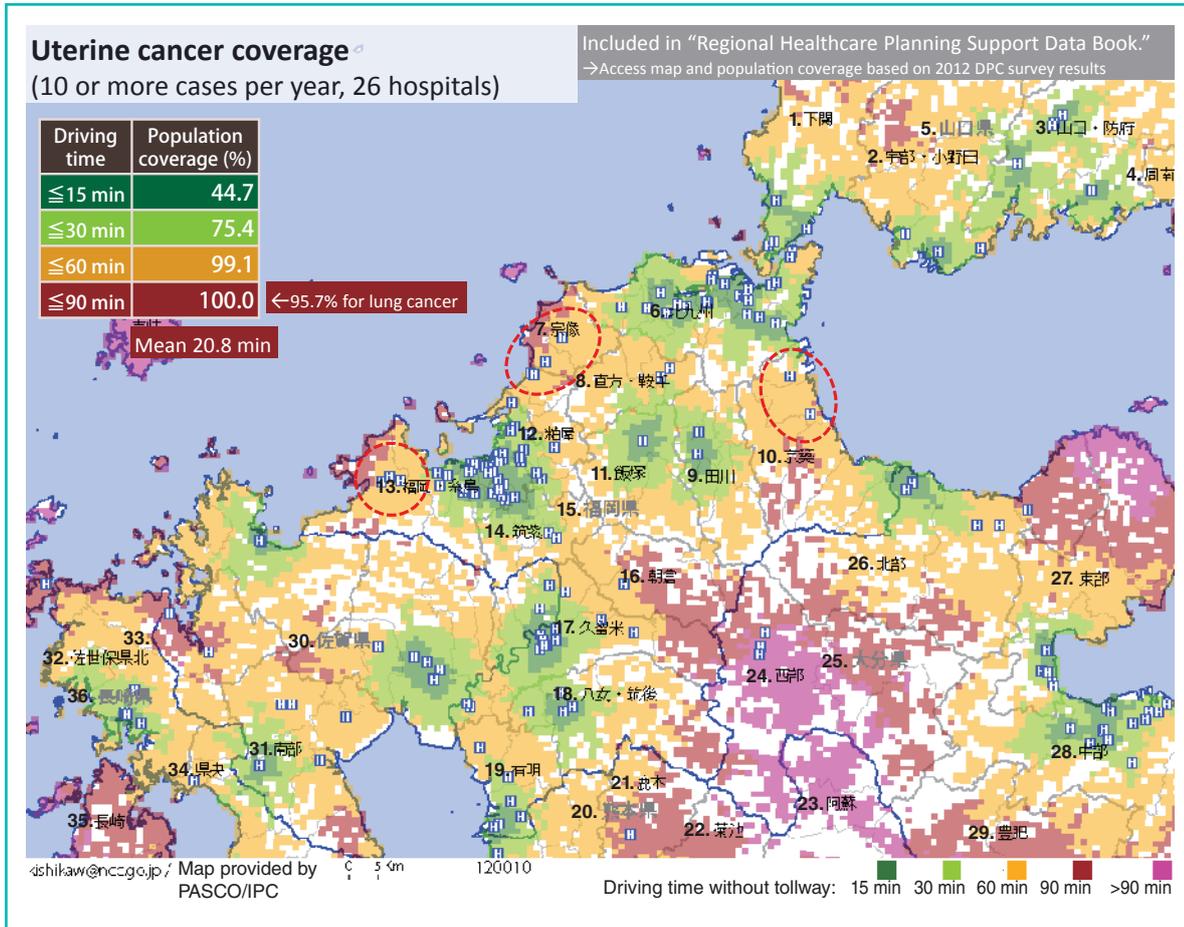
Fig. 11   Uterine cancer inpatient care coverage

1. Shimonoseki; 2. Ube/Onoda; 3. Yamaguchi/Hofu; 4. Shunan; 5.Yamaguchi Prefecture; 6. Kitakyushu; 7. Munakata; 8. Nogata/Kurate; 9. Tagawa; 10. Keichiku; 11. Iizuka; 12. Kasuya; 13. Fukuoka/Itojima; 14. Chikushi; 15. Fukuoka Prefecture; 16. Asakura; 17. Kurume; 18. Yame/Chikugo; 19. Ariake; 20. Kumamoto Prefecture; 21. Kamoto; 22. Kikuchi; 23. Aso; 24. Western area; 25. Oita Prefecture; 26. Northern area; 27. Eastern area; 28. Central area; 29. Hohi; 30. Saga Prefecture; 31. Southern area; 32. Sasebo; 33. Northern area; 34. Central area; 35. Nagasaki; 36. Nagasaki Prefecture

DPC data include deaths at the time of discharge, but there is no information about long-term prognosis after discharge. To obtain such data, additional effort is needed to collect them. In another case, if we want to investigate on adverse reactions of a certain drug, it may be possible to ascertain the presence of neutropenia, from a diagnosis recorded with the ICD10 code, but specifics on the severity of neutropenia remains unclear.

To overcome such weaknesses, we believe that the key to the better use of DPC data is to use them in rapid identification of patients and gathering of basic data, and extend them by adding data needed to answer specific research questions.

Collaborative use of data is an important concept for practical use of big data, as mentioned in Dr. Yamamoto's lecture. In collaborative research project with Chugai Pharmaceutical Co., Ltd., the National Cancer Center collected anonymized DPC data over a span of 5 years. There, we identified 13,000 patients on chemotherapy and proceeded to chart review for 884 colorectal cancer patients to clarify the type of treatment and their survival. Because we were successful with that attempt, we are now extending to 20 cancer centers around the nation to enlist colorectal cancer patients with DPC data and to enforce the data with additional clinical

Weaknesses of DPC data...

▸ Evaluation of treatment outcomes
- Limited data available on outcome (only death at discharge)
  - ▸ Additional clinical research data are necessary for analysis of long-term prognosis
- Coding for "adverse outcomes"
  - ▸ Limited information is recorded with ICD10 codes

▸ Detailed analysis by clinical stage/severity or by disease site
- File format 1 records limited data on severity, etc.
  - ▸ UICC TNM data is available, but accuracy evaluation is needed
  - ▸ Additional clinical research data are necessary (e.g., histologic type, degree of stenosis, labouratory test data)
- Consideration for pre-admission history or status
  - ▸ Time after onset, details for prior treatment, etc., are usually unclear

However...
adding complementary information to basic DPC data can accelerate research, and to make more effective use of data

Linkage of data is the key to successful research

Fig. 12   Weaknesses of DPC data

Current status of developing medical (big) data by the national government
- Progress in the development of the framework for collecting computerized data is evident
- However, anonymization and collection of data is performed for individual database, resulting in lower efficiency in operation and isolation of data

(Source: From the 7th Health/Medical Care Strategy Advisor Meeting (June 6, 2014). Provided by Dr. Hotta T.)

Fig. 13   Current status of developing medical (big) data by the national government
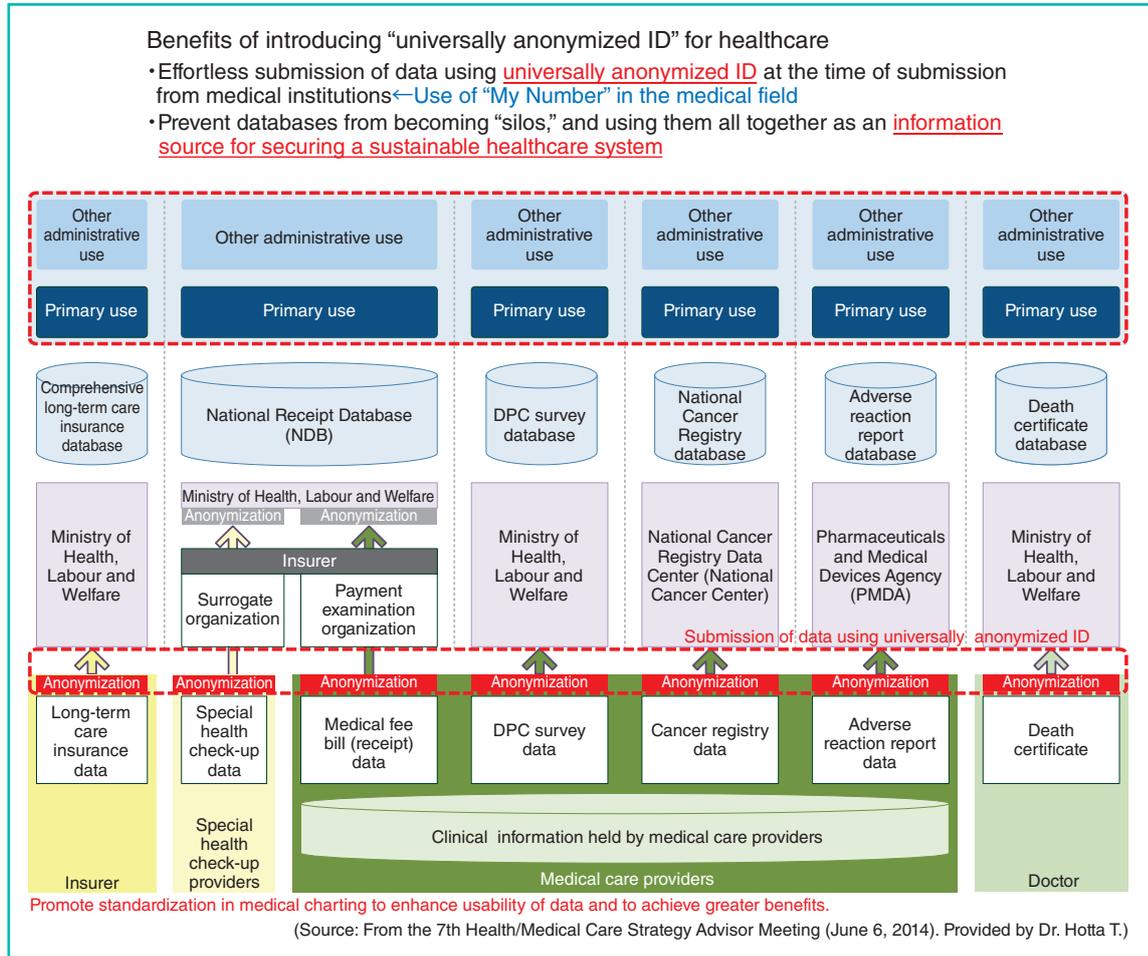
Fig. 14 Benefits of introducing "universally anonymized ID" for healthcare

and prognostic information from hospital cancer registry.

State of Development of Medical Big Data

What can the government do to promote the advancement of this type of research in the future?

Figures 13 and 14 are the materials presented by Dr. Hotta, President of the National Cancer Center, at the Health/Medical Care Strategy Advisor Meeting in June of last year.

As shown in the slide, various data are accumulated in this country through the development of medical big data promoted by the government (**Fig. 13**).

This raises the issue of the burden on the provider of data. They must either choose from

non-anonymized or anonymized data. If the data needs to be anonymized, the methods differ from a project to another.

At the same time, analysis of data is focused to project-dependent purposes and each process is segregated from a project to another, lacking in overall harmonization. Therefore, if we want to integrate the findings from multiple projects, we can only combine their results, but are unable to combine individual data for more streamlined analysis. That compromises the merit of using big data.

Recognizing such issues, it is desirable to allocate a universally anonymized ID at the time of data submission from medical institutions. If non-anonymized data are necessary for a project, it is a good practice to add minimal non-anonymized data to anonymized data. When assigning universally anonymized ID, we can
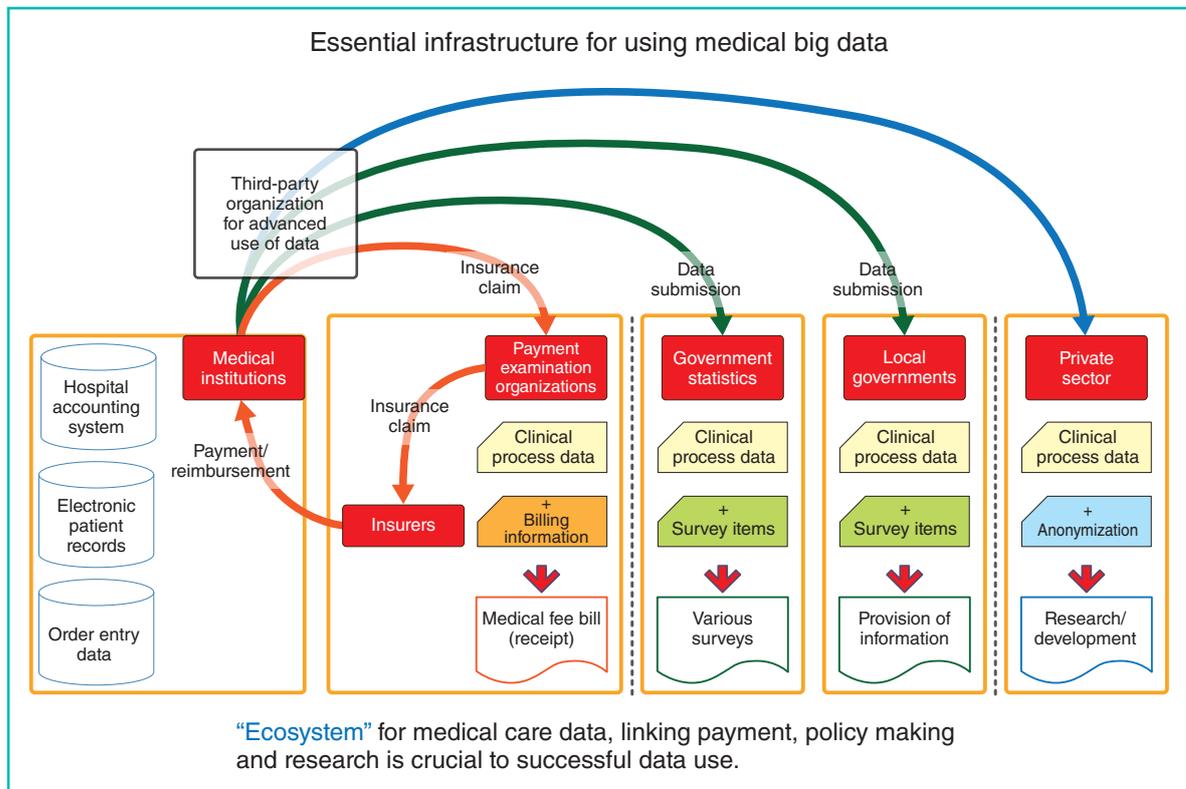
Fig. 15 Essential infrastructure for using medical big data

generate them for use in the healthcare sector, derived from the social security and tax number system (My Number System), as proposed by Dr. Yamamoto.

If the basic data are to be anonymized in this manner, and they are to be handled securely, they will become an essential information infrastructure for the nation. They will eliminate currently existing boundaries in anonymization and data processing, and will be an invaluable source of information to realizing a sustainable health care system (**Fig. 14**). But we should not forget the need for standardization in patient charting.

Major Issues in Using Medical Big Data

Another aspect that needs to be mentioned is on how data is submitted from providers. If possible, health care data should be once collected by a single organization and then routed to where

they are needed. Currently, providers submit the data individually for each purpose, i.e. reimbursement of medical fees, national government statistics, and local government administrative procedures or for other private purposes (**Fig. 15**).

In order to make maximal use of digitized health care data, we must build an ecosystem that is effective and efficient. It should cover activities in the government and research community as well as insurance claims processing. To make such system come true, special consideration should be paid in the process of future revision of the Private Information Protection Law or the Social Security and Tax Number Law. Then the fruit of the ecosystem can be shared among health care providers, patients and the public.

This is the end of my presentation. Thank you for your kind attention.

Healthcare and the Roles of the Medical Profession in the Big Data Era[*1]

Yuji YAMAMOTO[1]

Abstract

The accumulation of large amounts of healthcare information is in progress, and society is about to enter the Health Big Data era by linking such data. Medical professionals' daily tasks in clinical practice have become more complicated due to information overload, accelerated technological development, and the expansion of conceptual frameworks for medical care. Further, their responsibilities are more challenging and their workload is consistently increasing. As medical professionals enter the Health Big Data era, we need to reevaluate the fundamental significance and role of medicine and investigate ways to utilize this available information and technology.

For example, a data analysis on diabetes patients has already shed light on the status of accessibility to physicians and the treatment response rate. In time, large amounts of health data will help find solutions including new effective treatment that could not be discovered by conventional means. Despite the vastness of accumulated data and analyses, their interpretation is necessarily conducted by attending physicians who communicate these findings to patients face to face; this task cannot be replaced by technology.

As medical professionals, we must take the initiative to evaluate the framework of medicine in the Health Big Data era, study the ideal approach for clinical practitioners within this framework, and spread awareness to the public about our framework and approach while implementing them.

Key words   Big data era, Essence of medical care, Care range expansion, Data interpretation and traps, Initiative by professionals

What Big Data Means

In the following presentation, I will be discussing the practical challenges related to and providing examples of how Big Data should be used by physicians in clinical or general practice, ultimately leading up to my proposals on how we physicians should act as medical professionals in the Big Data era.

First, I would like to start by briefly describing what Big Data means. It seems that the phrase *Big Data* is also becoming popular among the mass media. However, the definition of Big Data is quite vague. As I understand it, the definition of Big Data or what it implies vary depending on the person who uses it. According to some, data that enables us to predict any future is called Big Data. Others say that any data that surpasses the processing ability and memory faculties of humans should be called Big Data.

Neither description is wrong. Maybe Big Data can anticipate anything someday. In the healthcare setting, however, even if we have data from the over 120 million people of Japan suggesting something, we physicians will always question whether we can honestly say to any given patient in front of us that this suggestion

from Big Data applies to him or her. In clinical trials and research, the amount of data handled already exceeds the humanly possible capacity for processing. In fact, when we adopt this second definition of Big Data—that is, an amount of data that cannot be processed by our natural human faculties alone—we find that Big Data is already being applied in some healthcare fields. However, there are some fields of healthcare to which Big Data cannot be applied so easily.

Current Healthcare Practice Settings Are Overloaded with Information

With that in mind, I believe that current medical practice is already overloaded with the "currently available" data. I have several points regarding this (**Fig. 1**).

For one thing, we must constantly make clinical decisions in our daily practice, but the amount of evidence, or the grounds for a decision, is increasing explosively. As already mentioned repeatedly, the amount of available data has far surpassed the human processing capacity.

As shown in **Fig. 1**, for example, thoroughly reviewing all published papers on echocardiography would take about 20 years for one person, assuming that that person reads 5 papers per hour. So, how can cardiologists begin practicing if they have to complete the current curriculum of 6 years of medical school and 2 years of clinical training followed by specialist training, while also reviewing all papers on echocardiography? There is just too much information.

Another thing is that the range of medical practice has been expanding. What I mean is, medical practice is no longer the simple process, if I may say so, of making a diagnosis and providing treatment. It now includes disease prevention and management, and health promotion.

One example of the expansion is the range of data linkage from clinical tests to a patient's

The volume of technology and knowledge is increasing
- Development of new drugs and medical devices
- Accumulation of evidence
  (over 200,000 papers are being published per year)
  • It will take 20 years for one person to read all papers on echocardiography at a reading rate of 5 papers per hour.
✓ **How can one's knowledge stay updated?**

The range of medical practice is expanding
- Diversified needs
  (covering everything from preventative care to long-term care)
  • Will predictability and professional duties to avoid risk increase?
- Promotion of "team-approach" in medicine
  (collaboration with different healthcare professions)
- Expansion of places in medical practice
  • Spreading to at-home care, industrial health, and everyday life
✓ **How do we define the medical profession in the ever-expanding healthcare field?**

The speed of healthcare environment change is increasing
- Medical technology advances akin to each passing second and minute rather than each passing day
- Speed-up in data exchange
  • The fine balance between the benefits of information sharing and disclosure and protection of personal information
- Rapid aging of the population structure
✓ **How do we respond and manage the external environment?**

Increasing volume of technology and knowledge

Expansion of the range of healthcare

Big Data

Rapidly changing healthcare environment

True nature of healthcare

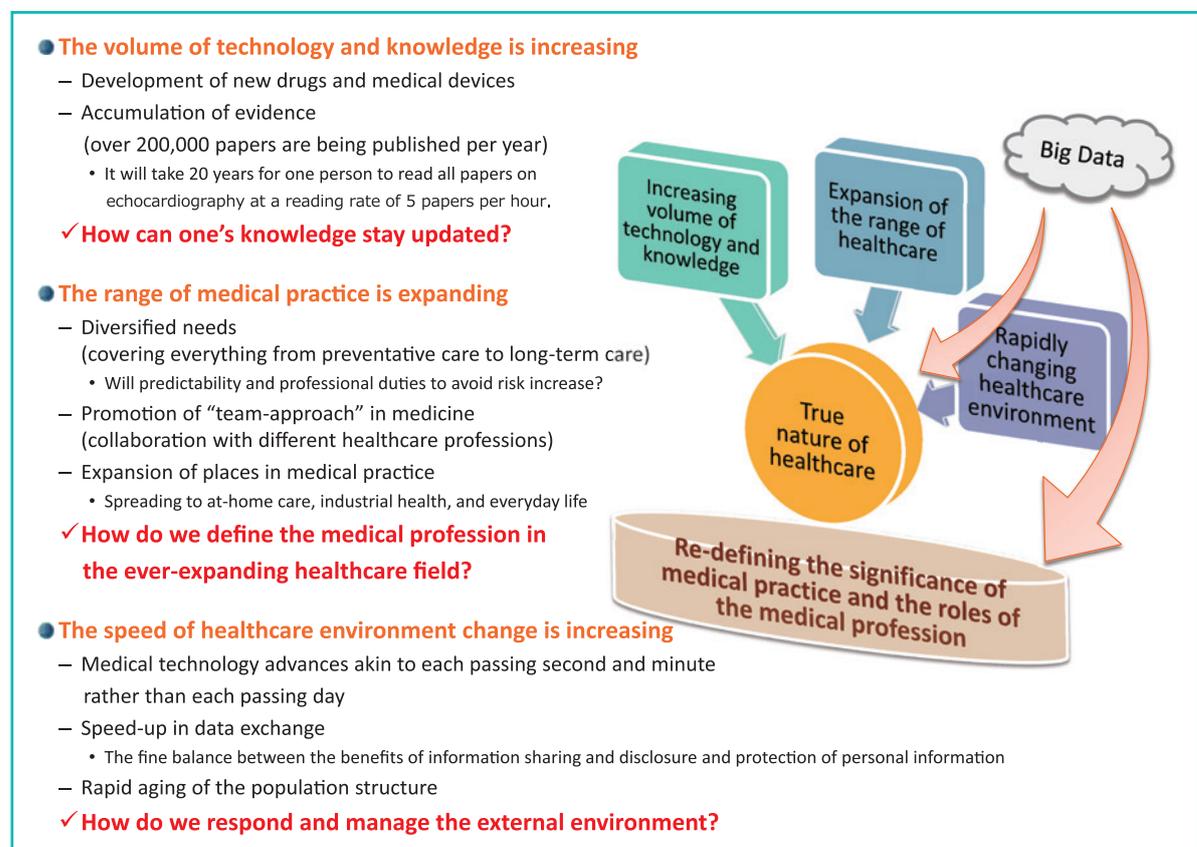Re-defining the significance of medical practice and the roles of the medical profession

Fig. 1 Tasks for the medical profession in the era of complicated healthcare and information overload

health information, such as body weight changes, pedometer records, and calorie intake, which many people have to constantly manage nowadays. Alternatively, locomotive data such as a walking speed can be linked to clinical data in daily life function assessment or long-term care. "Linking data" of this nature is becoming increasingly popular, and it is overloading us.

In the world of healthcare—where tasks require the collaboration of many professionals—physicians must make various judgments. However, not only is the amount of information increased by such "linking data" but also is the range of duties for which physicians are responsible. Thus, an issue of considerable significance to us physicians in the Big Data era is how to consider and manage this expansion of medicine as a medical profession.

In addition, technology is progressing very quickly. Technological development in medicine is more like each passing second and minute rather than each passing day—but how can we learn to use the technology produced? Also, how can the effectiveness of the used technology be verified? We are facing overwhelming tasks. When we consider these issues to be part of our contribution to society as a medical profession, we must revisit "what constitutes the essence of medical care" and reevaluate the significance of medical care and medical professions in society. I believe now is a good opportunity to do that, and it is also a demand of society.

How We Can Utilize Big Data

Based on these understandings, today, I think we should consider how we can autonomously utilize Big Data in medical care and how we need to take initiatives in this issue, rather than how Big Data can predict the future or how large-scale health information can change medical practice.

Medical practice has always existed alongside information, and it has developed by accumulating information. Now, as shown on the left side of **Fig. 2**, we are part of a cycle of technological development in medical practice and promoting those developments in society. It is time that we start from scratch in thinking about how Big Data should be used.

I would like to start with the very basics of healthcare—namely, that there are several players in the healthcare community (**Fig. 3**). Many of the people who are here today probably belong to the "care providers" box in the center of this figure, but, as I mentioned, the range of care provided has expanded quite considerably in recent years. Also, along with the range of care, the number of industries that people consider to be involved in healthcare is increasing.

The good side is that self-recording of lifestyle factors and daily habits is becoming increasingly possible. Thanks to this, data such as blood glucose levels and blood pressure can be collected more easily than before.

On the other hand, concern has arisen over the continuous appearance and disappearance of pseudo-healthcare services with poor grounds.

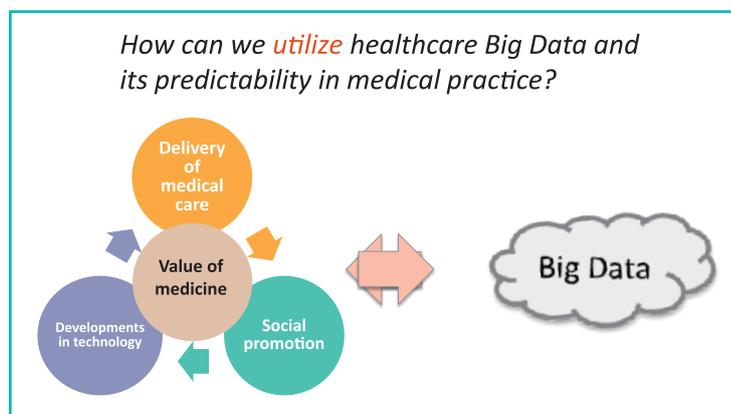*How can we utilize healthcare Big Data and its predictability in medical practice?*

Delivery of medical care

Value of medicine

Developments in technology

Social promotion

Big Data

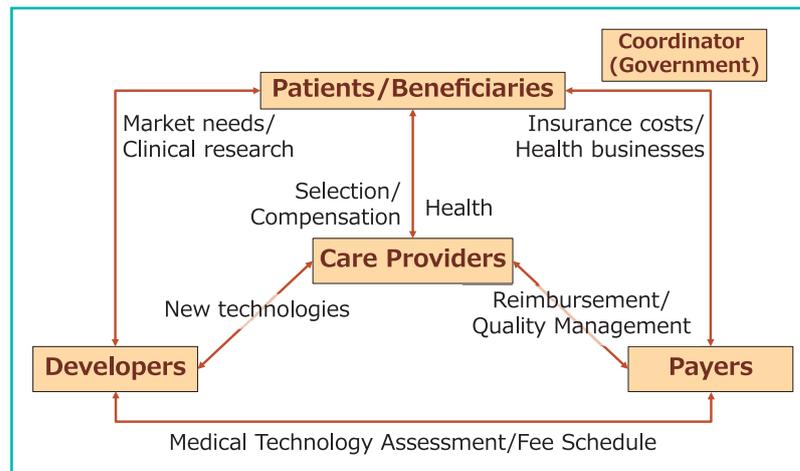**Fig. 2 The "problem" that clinical practitioners must consider**

Fig. 3   The 5 players and the power balance in the healthcare industry

How should we respond to this as a medical profession? As previous presentations have mentioned regarding the protection of personal information, we must think about the safe handling of medical information as professionals.

The people involved in the development of new medical technology, including pharmaceutical companies and research institutions such as medical schools, have also begun using Big Data. As I understand it, the era for considering how Big Data can be used to devise a new framework for medical practice and new healthcare services has already begun for these people as well.

Let's take the example of developing a drug. In the past, hypotheses were made and the drug efficacy was verified only in an experimental environment under certain controlled settings. Nowadays, the trend is to verify the drug effectiveness in an environment that closely resembles the real world. Study results obtained in that fashion can actually change diagnostic criteria and even the concept of diagnosis itself. In the world of cancer treatment, the way a diagnosis is made is gradually shifting from using an individual's conditions and test results to identify the disease to using genomic pathology and the subject's reactivity to specific treatment methods.

Now, we name the cancer by the organ that presents malignant neoplasms. Someday, we may begin to categorize cancer types by the types of drugs that affect them, such as a type of cancer on which a gene-targeting drug works well and that happens to be on a certain organ.

With regard to the "payers," a number of previous speakers today have talked about the topics of health insurance claim data and DPC data. The data that payers have been using when processing insurance claims to reimburse medical fees are likely the easiest entry point for Big Data application.

Although there are limits due to the nature of the data, there is a lot to learn from Big Data, as Dr. Ishikawa mentioned earlier. If we can learn what "best practice" is, promoting it in the medical practice community as quickly as possible may require the collaborative efforts of both us care providers and the payers who accumulate data.

The government would want to prioritize financial resources in order to prevent cost soaring and encourage them to pursue the financially ideal healthcare. It is highly important to know who will take the initiative in Big Data application.

The people of Japan are patients to us and beneficiaries of healthcare. As medical practitioners, we must not forget that one of our goals is providing proper medical practice and healthcare as promptly and effectively as possible to these people. That said, there are still many issues regarding the purposes and challenges of using information in the era of Big Data. For example, the genetic testing business is popular these days, but how can one separate the good ones from the bad? How and what kind of information becomes a part of Big Data is also one of the many issues that must be resolved.

The Paradigm of Healthcare Is Changing

Now that I have talked about the players in healthcare, I would like to list 3 points regarding what I consider to be minor changes in recent healthcare and medical practice (**Fig. 4**).

The first point is that healthcare has changed from being "extraordinary" to being "ordinary." Medical care in the past, either for inpatients or for outpatients, was usually practiced in a world separated from everyday life. Nowadays, however, the borders that separate everyday life from life with illness have become quite ambiguous, as the example of lifestyle-related disease shows. So, how do we go about collecting health information that closely corresponds to everyday life? Also, who would use this information, and how can it be used? In that sense, medical care is increasingly becoming a part of ordinary everyday life rather than an extraordinary part of life. Another thing to investigate, which is a slightly different topic from today's theme, is the rationale of using an insurance system for paying healthcare practice. This should be examined in light of the fact that we live in an age wherein almost everyone receives care from a physician at least once in his/her lifetime.

The second point is that the trend of healthcare is shifting from treating disease to managing overall health. The Growth Strategies of the Government of Japan have also gradually presented this element. In modern medicine, we can prevent and/or predict disease to a certain degree, especially chronic diseases. In this era, what can data show about the timing of disease onset? Also, when should a predicted risk inferred from data be told to a potential patient, and when should his/her care start? The time to study those issues will soon arrive.

The third point is that healthcare as a concept is shifting from being a cost to being an investment. For some reason, the healthcare expenditure has long been considered a cost, or a social burden, which has always made me feel unsettled. Healthcare is nothing more or less than an investment in health. We physicians are making contributions to national health in the form of medical care, and calling it a "cost" is rather unfortunate.

On the other hand, I also believe that the medical profession should be held accountable for explaining to the Government and communities the contribution we are making using specific figures in the future. I consider this to be an additional task for physicians in the era of Big Data.

"Extraordinary" → "Ordinary"
- Almost everyone has been seen by a physician at least once in life.
- Goes beyond the insurance coverage for "unforeseen situations."
- From "non-routine care" to "routine health maintenance."

"Treatment" of disease → "Care" of health
- "Prediction" and "prevention" are possible in modern medicine to some extent
- Intrinsic value lies in maintenance of "long-term health" rather than in "care for serious disease"
- Needed medical care is care that gives peace of mind to young people and joy to those in middle/old age.

Social "cost" → Public "investment"
- Healthcare as an investment in the country and society
- Not bound by the "technical prolonging of life" stories of status quo businesses
- The ultimate value is health maintenance, and the evaluation of achievements and competition is promoted.

Fig. 4   The paradigm of healthcare is changing

Filling the Gaps in Healthcare

So far, I have raised various issues and problems, but now I would like to turn to bridging the gap between the healthcare that is actually being practiced now and the ideal healthcare that should be practiced using Big Data, along with some specific examples (**Fig. 5**).

On **Fig. 5**, the right-hand side shows some of these examples. Please note that these are purely my personal opinions on what ideal healthcare comprises; they do not have official or public significance in any away.

The left-hand side of the figure depicts the healthcare that is currently practiced, such as the problem of the shortage of healthcare professionals compared to the number of patients. The shortage of physicians is an issue in many places in Japan, but how can we solve this problem of quantity using Big Data?

Another issue is the problem of quality, as I have repeatedly mentioned today. The demand and expectations of society for healthcare is only growing larger, but are we really equipped with the resources and information to meet them? Also, is the system in place capable of handling them? These are issues we have to consider.

For example, how can we incorporate health maintenance and support into current healthcare practice? Also, how can we utilize Big Data when we want to take a step beyond "free access" healthcare, which is an extremely precious asset for the Japanese healthcare system, to "best access"?

Another thing relates to the medical fee schedule—namely, whether Big Data can be used to secure remuneration and appreciation for physicians, which physicians naturally deserve as a profession for providing high-quality medical care. Also, how can we offer fair and accountable medicine? I would like to explain these issues one by one using data from a few case studies.

How We Can Promote the Best Access Approach

How can we promote health maintenance and support and the best access approach in medical care? I have been entrusted with certain health data for some statistical analyses, one of which is a retrospective cohort study on the health checkup data of 450,000 people (**Fig. 6**).

These results are from 150,000 people with 3 years of health checkup records, and they show that about 90% of people whose LDL cholesterol was higher than a certain level answered that they had remained untreated. Their health checkup reports all had comments specifically mentioning that their level was abnormal and
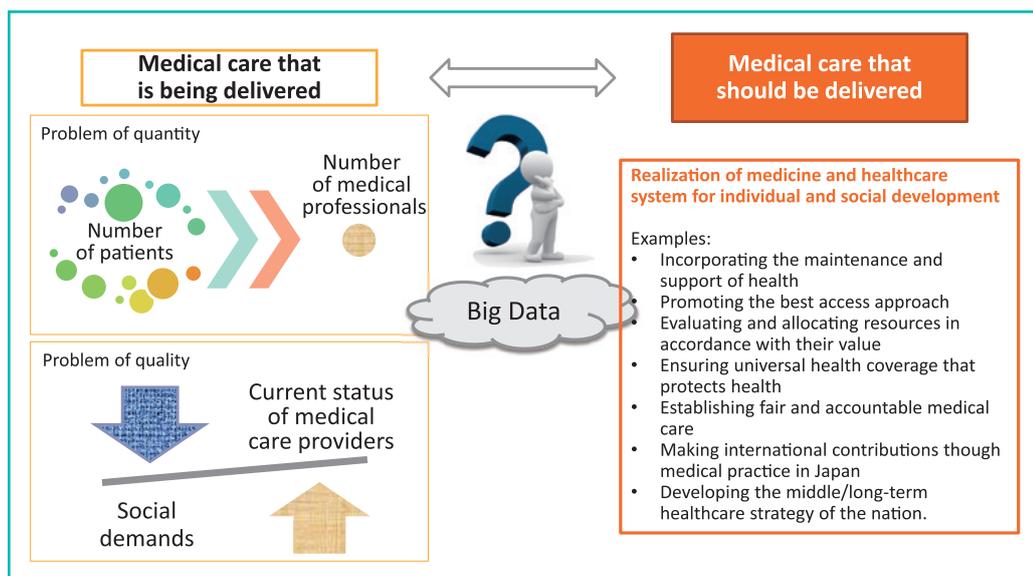

Fig. 5   Used as a tool to bridge a gap that cannot be overlooked

- A follow-up questionnaire survey on 450,000 person-years

- Of the 15,665 cases with LDL-c of ≥160 mmHg in FY2010:

  ✓ **90.1%** answered that they are **untreated**
  ✓ Of those, **90.6%** remain untreated in FY2011
  ✓ Of those, **91.5%** remain untreated in FY2012

- **90%** of those who received treatment showed LDL-c level **improvement to <160 mg/dL**

To produce the best access in medical care, what kind of information and communication must be in place? Who will be responsible for this?
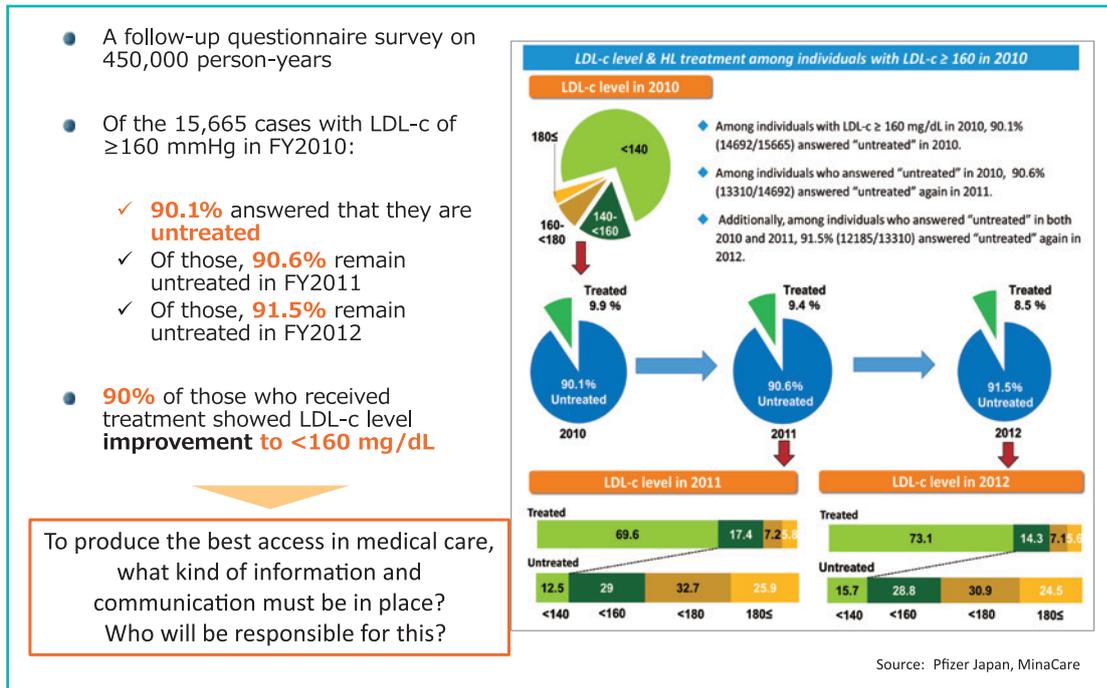
Source: Pfizer Japan, MinaCare

Fig. 6   Accessibility to medicine: who, when, and where

that they should seek medical consultation; however, only around 10% of them actually visited physicians.

The following year, their LDL-c level was still high, but again only 10% sought medical consultation. The same goes for the year after that. Health checkups are very popular in Japan and people see their health data every year—and yet, only a small proportion of people actually access medical care. Even a well-known risk factor such as cholesterol goes untreated in 90% of the people who should be treated.

So, those of us who are physicians involved in clinical practice must think of how we can provide available information to patients in a way that prompts them to act. We must also think of who should be telling them. While a single personal computer, which almost everyone has nowadays, can do the relevant data computation, it cannot tell the user how to communicate the results to others.

A Gap between What the Data Show and the Reality of Seeking Medical Consultation

A case study of diabetes is shown on **Fig. 7**; the

Y-axis shows the hemoglobin-A1c (HbA1c) level, which corresponds to severity of diabetes. The higher it is on the Y-axis, the more severe the diabetes is. The horizontal dotted line in red is the severity standard of the Japan Diabetes Society. The computation formula is slightly different now, but this line basically indicates that the score is not very good for a diabetic patient—namely, a person is not managing his diabetes well if his/her score is above this line.

You can see numerous blue circles and red dots; each represents one person. The size of each blue circle represents the medical expenses related to his/her diabetes for a year. Red dots indicate no expense, meaning that the person has not visited any doctor. The X-axis is the age. You can see that a certain number of people go untreated even though their score is high enough to indicate severe diabetes and they are above a certain age. More specifically, about 1/3 are red dots.

When physicians see these data, I believe that they would naturally develop a sense of crisis that this gap between what the data show and the reality of seeking medical care must be somehow filled.

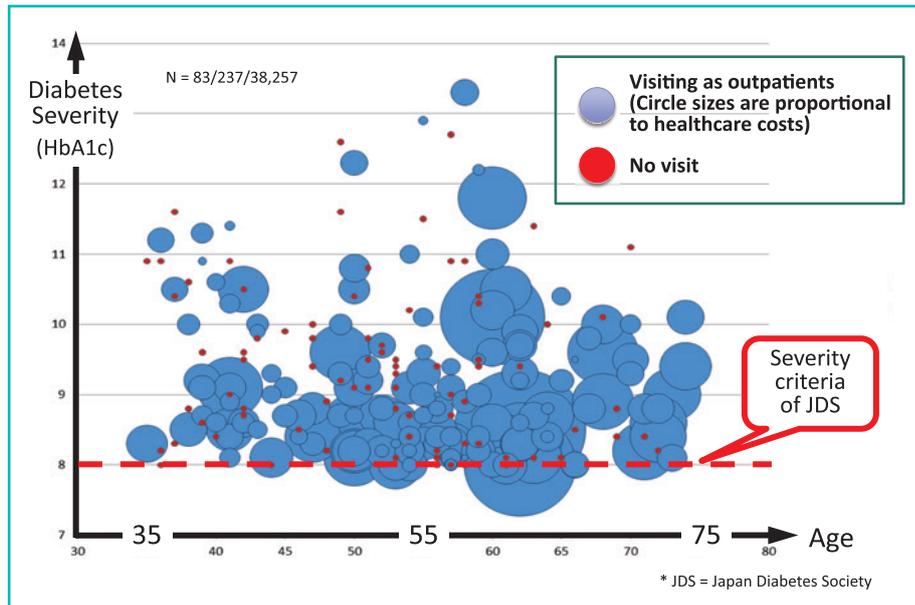Now, let's continue to the drug treatment

Fig. 7   Status of hospital/clinic visits for poorly controlled diabetes

Disease category	Response rate
Pain management by analgesics...	80%
Asthma..	60%
Arrhythmia..	60%
Schizophrenia..	60%
Migraine (prevention)	50%
Rheumatoid arthritis..	50%
Osteoporosis..	48%
Hepatitis (type C)...	47%
Alzheimer's disease..	30%
Cancer..	25%

Source: Spear, Brian B., et. al., " Clinical Application of Pharmacogenetics," Trends in Molecular Medicine, vol. 7, issue 5, 2001, pp. 201–04. (The source of data in this article was the Physicians' Desk Reference, Thomson Health Care.)

Fig. 8   The tools necessary for medical practice are also insufficient

data based on response rate. The data shown on **Fig. 8**, which are not from Japan, suggest that the response rate was unexpectedly low. Of course this does not apply to all cases, but I believe you all have experienced a difference in efficacy among drugs, such as "Company A's cough medicine works better than Company B's," or "this brand of painkiller works better than that one." However, even analgesics only work 80% of the

time overall. Although it varies by the type of cancer, the data show that cancer drugs only work in 1 out of 4 cases.

One dilemma for physicians in clinical practice is that patients simply will not come to clinics or hospitals. Even when people do come to a clinic or hospital, the data we have available on the response rate tell them that we have only these weapons with low response rates—so, what

should we do? This is one of the many things we must consider in the upcoming era of Big Data.

Making Use of Data in the Health Management of Local Communities

Next, I will talk about how we can use data for value-based evaluation and resource allocation as part of the universal health coverage to protect health.

Using the data I have been entrusted from the insurer from the previously mentioned diabetes case, I can create a status map of treatment and access status (**Fig. 9**). Please note that the data shown on the figure do not really belong to the community shown on the map; I am simply using a map I found from the Internet homepage of this community. So, please take this merely as an example.

The data show the number of patients across areas, including not only those who are actually receiving care but also those who should receive care but remain untreated, as well as those who are potential patients. When such information becomes available, local medical associations will realize that there are many people with high LDL cholesterol who do not seek treatment in

their areas, and thereby can develop a community healthcare plan, such as adding 1 more day for outpatient care by specialists.

If local medical associations can show the effects of such effort in real numbers, it will help convince local governments and residents that the best access to medical care has been improved and that the health level of the community as a whole has been elevated. This particular example can also help convince people that healthcare is not a social cost but a public investment.

How to Approach Medicine in the Big Data Era

Let's move on to the next topic: fair and accountable medicine.

I became a physician in 1999. Many lawsuits on medical malpractice were taking place then, and my generation was exposed to public distrust toward medicine. I believe professional accountability will only become increasingly significant for physicians from now on.

Until now, the accountability of medical evidence began with case reports, as shown in **Fig. 10**. Experts gathered at the meeting of a medical
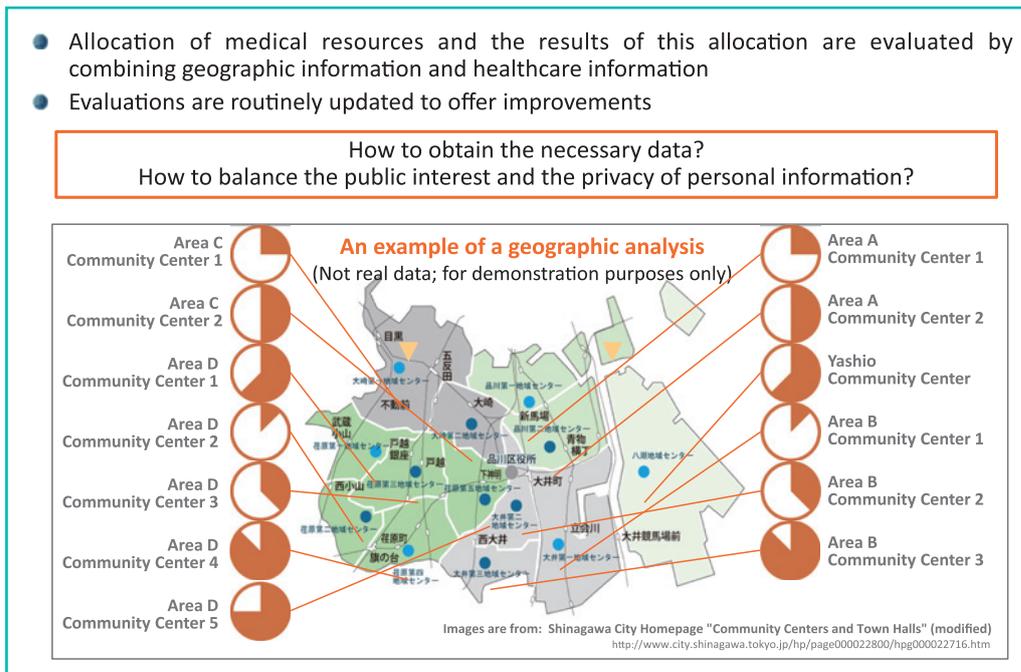

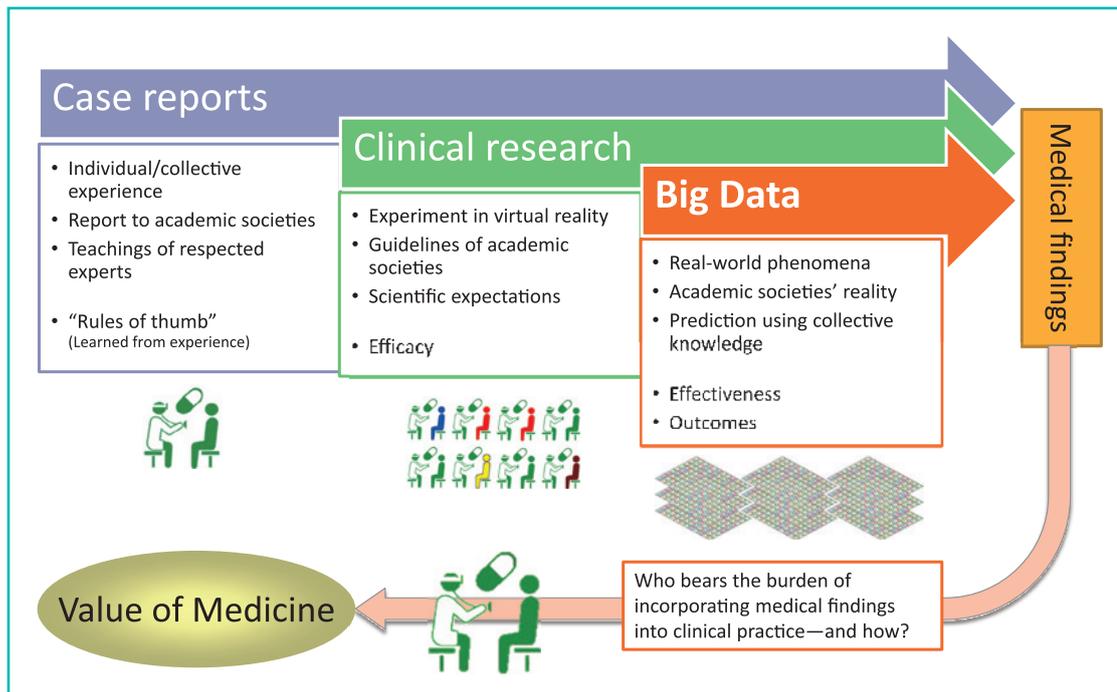**Fig. 9 Data for self-management of health and community development**

Fig. 10   The technology and concept of obtaining new medical knowledge

society, and the most respected ones shared their case studies and rules of thumb with the rest. This is how medicine gradually grew, and I believe everyone will probably agree with that.

Then, the idea of evidence-based care sunk in, and treatment and its effect in clinical research or trials, wherein real-world conditions were simulated, began to be highlighted at a certain experimental level. Guidelines were developed in this fashion by medical societies, wherein they aggregated experimental results that can be called scientific expectations and efficacy. This approach lasted for years.

In the era of Big Data, however, I believe we can come up with a better concept of healthcare—or best practice—by viewing it as collective knowledge and collecting what is really happening in society, how well guidelines are made known or observed, and how various medical institutions actually carry out the practice of medicine. Those experimental values that were once considered so-called "efficacy (or potential effectiveness)" will actually be regarded as "effectiveness (or practical effectiveness)."

For example, let us assume that there is a drug that is supposed to work on 60% of patients according to some studies, and the drug was given to 5 to 6 people but produced no effect at all. Should the 7th patient be given the same drug? This is always a dilemma for the medical profession. Big Data would enable us to see that the studies with good results were rather atypical, and that the overall opinion among clinical practitioners is that this drug does not work too well—or vice versa. When such a time comes, the current approaches for guidelines and clinical research designs will begin to change. Approaches for selecting medications and the speed of spreading best practice may change as well.

Meanwhile, medical professionals must work on how to explain those medical findings obtained from Big Data to the patients face to face, which is a never-ending mission for us. No matter how large the Big Data grows or how much technology advances, it is the duty of medical professionals to carry out this task.

So, the technology of Big Data can be a very powerful tool in medicine. On the other hand, it will at the same time force us to seriously consider what the purpose of medicine is—and what the ultimate responsibilities of medical professionals are.

Gaps in Medical Practice That Must Not Be Overlooked

Let me elaborate on the topic of accountability a little further. **Figure 11** shows 3 examples of gaps between the reality and ideals in medical practice that were discussed around 10 or more years ago.

Shown on the left is the overuse of medical care, or overcare, to put it simply. The middle is the underuse of care, meaning that care is needed but is not sufficiently provided. This could simply be the case that a patient right in front of you deserves more cordial care, or the number of outpatients in a certain area is beyond the local capability and therefore outpatients do not receive enough care or suffer from poor accessibility. Either case can be considered underuse.

Then, there is the misuse of medicine in the first place—that is, providing inappropriate care. This is not a main topic of my presentation today, but I believe such misuse will likely be reduced to a certain extent if Big Data or IT is applied in clinical/hospital practice. It is also possible that what was once considered the standard treatment will be proven ineffective and a new treatment is established, which means that such misuse will simply become a case of the knowledge being outdated in the future.

Then, how should we update our knowledge?

As I mentioned at the beginning, one cannot spend 20 years just doing nothing but reading papers. So, how can we provide timely updates for truly important information? This is another aspect of Big Data application that must be taken into consideration if we are to fulfill our accountability or responsibility of verification in medicine that the upcoming era will require us to.

Physicians' Competence to Be Tested

Figure 12 is about a slightly different topic; it is an extreme example of how medical findings obtained from data can be used in practice. "Is it possible for this group of 4 persons to cross this river?" is the question.

Data in textbooks or papers are described like this: The average height of this group is 1.7 m, and the average depth of this river in front is 1.6 m. So, one would naturally think that everyone should be able to cross this river. Similarly, we naturally employ a system of medicine based on "this treatment is good on average." There is nothing wrong with this approach. However, if this group consists of 2 persons who are 1.9 m and 2 persons who are 1.5 m, it poses a problem. It is possible that 2 may die while 2 will successfully cross the river. Now, what if the deepest spot of the river was 2.2 m? Then, everyone

- Gaps between medical care that *should be* delivered and that which is *actually* delivered
- Gaps between societal demands and medical care delivered by the industry

Overuse	Underuse	Misuse
• Unnecessary medical care is provided • Example: Giving drugs to patients whose conditions will improve over time • There is a risk of adverse events and unnecessary increase in cost.	• Needed medical care is not sufficiently provided • In the USA, over 90,000 people reportedly die each year from underuse of medical care for chronic diseases such as hypertension	• Inappropriate medical care is provided • In the USA, about 40,000 to 100,000 people reportedly die from the misuse of medical care

Sources: The Essential Guide to Health Care Quality (2007)
To Err Is Human: Building a Safer Health Care System (2000)

As medical professionals,
care integrity (accountability and responsibility for verification and improvement)
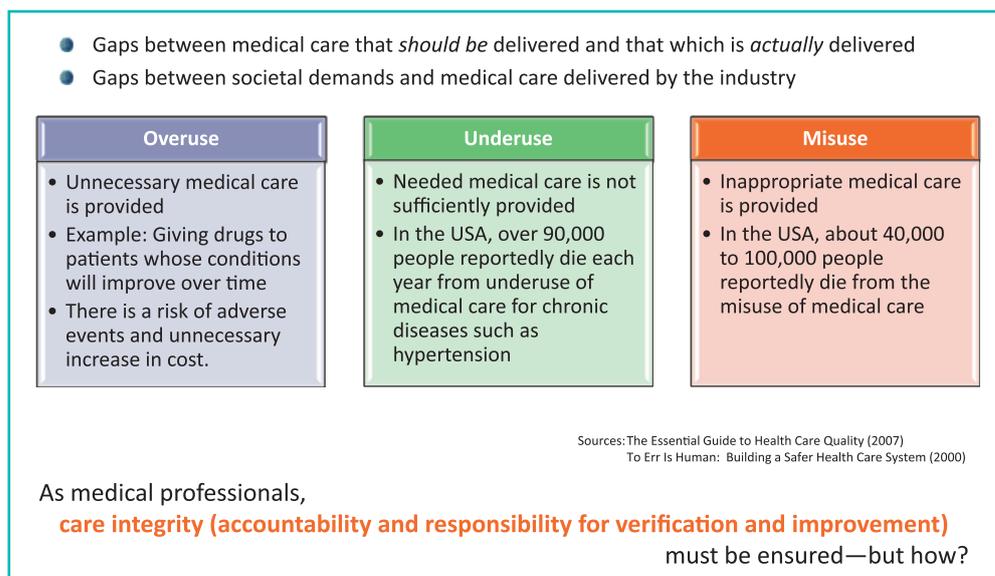must be ensured—but how?

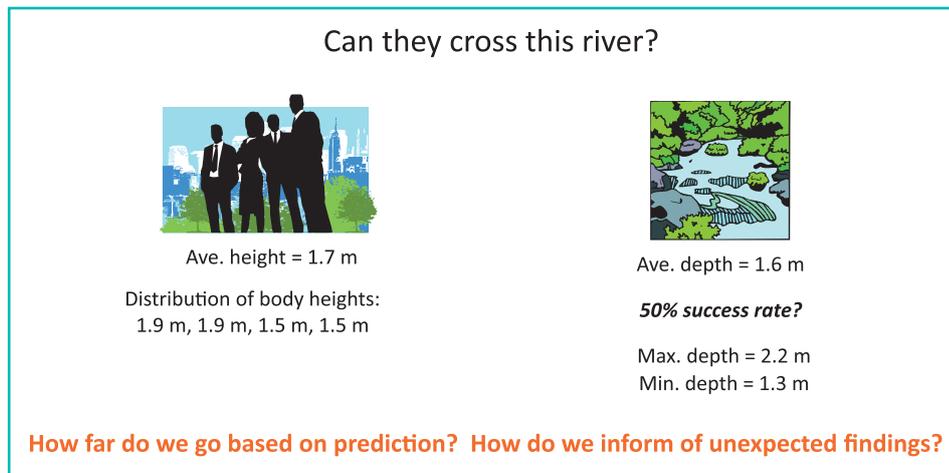Fig. 11   Gaps in medical practice that must not be overlooked

Fig. 12   Numbers can play tricks and mislead one's decision-making

would die. Or, maybe, everyone could cross the river if they stayed in the shallow areas, which has a depth of 1.3 m.

When we take a case-by-case approach in decision-making instead of using average values from existing clinical research, these kinds of "details"—called the "grain size"—can make a considerable difference. As the grain size decreases, the chance of coming up with a clinical pathway that no one could imagine or questioning the original diagnosis increases. In other words, the medicine that was previously trusted may be proven untrustworthy. If it actually happens, how we inform patients is a big challenge for those of us in clinical practice.

Let's say that the deepest spot is 2.2 m and the shallow areas are 1.3 m, but you do not know the safe route. One approach is to leave the decision-making to the individuals; you could inform a 1.9 m person that the deepest spot is 2.2 m and ask if he/she is willing to try to cross. Another approach is to advise the person to not cross the river since he/she will be carried away if the person happens to cross at the deepest spot.

In the era of Big Data, wherein medicine will use information to predict likely outcomes, how physicians inform patients about the new information and how we make our decisions will become very important points. We would need to bear these points in mind in our profession when using this powerful tool called Big Data.

Changes in Technology Development by Big Data

Now, I would like to stop talking about the demand side of the story, and talk more about technology advancement (**Fig. 13**).

When a new drug is developed to treat a disease, a clinical test would be conducted with a certain number of patients (or subjects); say, for example, that 2 out of 6 patients did not show much improvement. We would then conclude that it is probably a good drug since it worked for 2/3 of the subjects, and we would then tell those patients in green that this drug works well. In the Big Data era, however, the number of cases to deal with will instantly increase.

When the proportion of patients that this drug does not work on exceeds a certain number, a new drug must be developed to provide a cure for those who could not previously be treated—this will likely become the mainstream of new drug development in the future. Earlier, I mentioned that there will be a case in which the original diagnosis will be questioned by Big Data; this way of new drug development is an example.

In the upcoming era of Big Data, what was previously believed to be the same disease could be shown to be different diseases based on patients' responsiveness to a given treatment. The advancement of medications and medical equipment is not really today's theme, but I want to point out that it will enable a more pinpointed
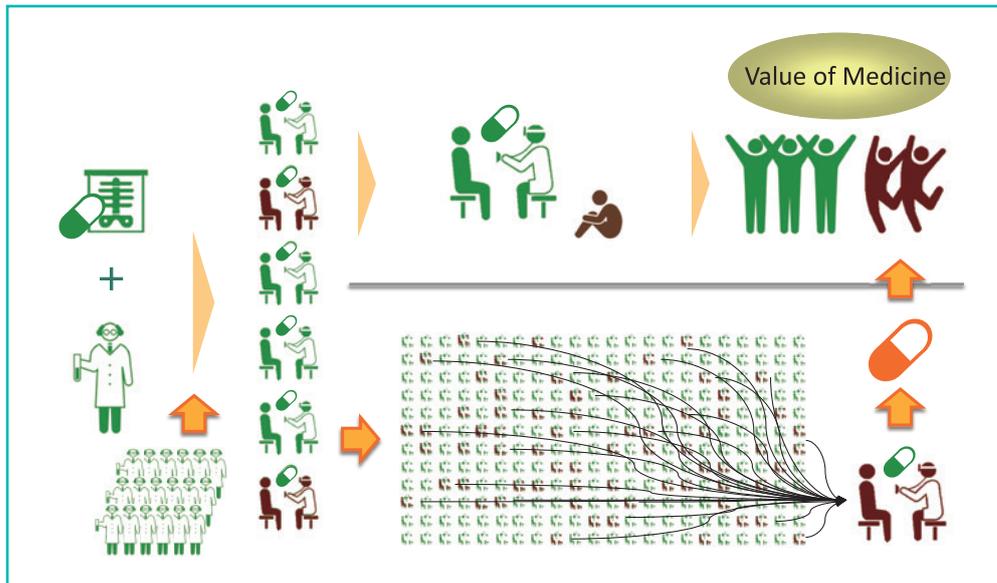
Fig. 13 Changes in technology development by Big Data

approach in treatment and increases the significance of atypical cases.

Responsibilities Entrusted to the Medical Profession in the Big Data Era

To wrap up my presentation today, when databases are linked and a large volume of data become available as Big Data, medical professionals have many things to consider regarding the success or failure of Big Data application. Notably, those things to consider could be more serious than the use of Big Data itself (**Fig. 14**).

As the 2 previous lecturers mentioned, there are many challenges in the Big Data era at different stages, such as how to obtain certain data and how to analyze and use that data. For the medical profession, one challenge is the potential traps in data interpretation—I showed this in the river-crossing example. A dataset itself has certain limitations to begin with, and therefore we cannot simply use whatever Big Data suggests as the golden rule.

We also need to consider the medical system we have fostered up until now and investigate the ways in which Big Data can contribute to health for the population and to medical practice for social development by using the appropriate grain size, knowledge, range of application, timeliness, and manners of utilization.

The last point I want to make is that we will have to take initiative as clinical practitioners or medical professionals in the Big Data era (**Fig. 15**). Big Data will make what was previously invisible visible and relate things that were believed to be unrelated before. Furthermore, Big Data will allow us to predict the outcome of a clinical course from a clinical diagnosis, and it will change the balance between prediction and decision in medical practice.

On the other hand, someone will have to bridge the gaps between human data and the living human in the medical practice of this era. This responsibility is, and always will be, entrusted to medical professionals.

No matter how good a data analysis is, the so-called human traits—originality, pride, laziness, mistakes, etc.—may never become fully encoded as data. Of course, those people in IT or data management may claim that those human traits can be predicted from the data. Nevertheless, how to encode human qualities as data remains a challenge from a technical perspective as well. That being the situation, I believe there are many things that medical professionals must do.

We have no choice but to use Big Data. As we have seen in the last several years, we live in a time wherein the volume and nature of data change quickly, as does the development of
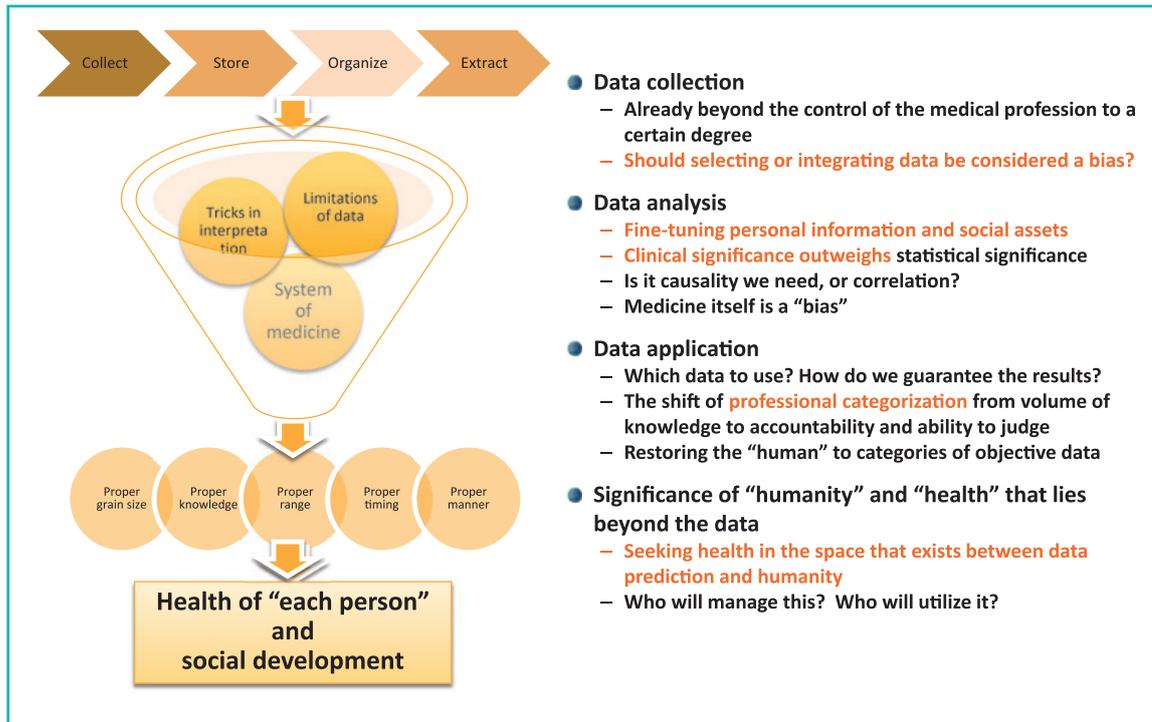
Collect → Store → Organize → Extract

Tricks in interpretation

Limitations of data

System of medicine

Proper grain size | Proper knowledge | Proper range | Proper timing | Proper manner

Health of "each person" and social development

● **Data collection**
- Already beyond the control of the medical profession to a certain degree
- Should selecting or integrating data be considered a bias?

● **Data analysis**
- Fine-tuning personal information and social assets
- Clinical significance outweighs statistical significance
- Is it causality we need, or correlation?
- Medicine itself is a "bias"

● **Data application**
- Which data to use? How do we guarantee the results?
- The shift of professional categorization from volume of knowledge to accountability and ability to judge
- Restoring the "human" to categories of objective data

● **Significance of "humanity" and "health" that lies beyond the data**
- Seeking health in the space that exists between data prediction and humanity
- Who will manage this? Who will utilize it?

Fig. 14 Definition of "medical profession" can influence data utilization

In the Big Data era...
● What was previously *invisible* is starting to become **visible**
- Inevitably, there will be some bias, but the gap between virtual reality and actual reality will begin to be bridged
● What was previously believed to be *unrelated* is starting to become **related**
- Big Data will become more powerful as a tool, particularly in a vast and static system
● The **balance** of prediction and decision is beginning to **change**
- Weak causality, with sufficient data, can allow mechanical forecasting of an outcome before one makes a decision by a rule of thumb

Medical care in the Big Data era:
● **The future predicted from human data must be converted back to the future of the living humans; this remains the same**
- While obtaining collective knowledge, medical professionals should be responsible for applying it to individuals and informing patients, and for the outcomes.
- Human qualities, such as originality, laziness, pride, or mistakes, need to be incorporated into medical practice as well—but how?
● **The quantity, quality, analysis, and application of data continue to develop, so medical professionals must cope with these changes**
- There are responsibilities and necessary skills for medical professionals—namely, **to not be changed** but **to change**
- Non-medical skills and cooperation/collaboration with other professionals to realize it

Each physician should voluntarily re-define the value of medicine, re-examine the guidelines for professional conduct, and send out messages based on our new role.

Fig. 15 An era in which medical professionals are asked to take the initiative

methods of analysis and application. There are areas in which we must also change in response to these changing times.

How do we define future medicine now? How do we approach Big Data application as action guidelines for the medical profession?

The time has come that we must examine those issues and send out messages related to these issues of our own accord. What we need now or soon is a starting point, a chance to use Big Data as a tool. I would like to conclude my talk with these remarks. Thank you for your attention.

From the Editor's Desk

Meeting for a home-coming report by the Takemi fellows

The two Japanese Takemi fellows who were selected by the Japan Medical Association (JMA) presented their research results at the JMA Building on July 26, 2016. These two have studied for 11 months at the Takemi Program in International Health at the Harvard T.H. Chan School of Public Health in Boston, USA from August 2015 to the end of June 2016. Each of them passionately presented their research report.

The Takemi Program, established in 1983 at the said graduate school to honor the former JMA President Dr. Taro Takemi's achievements in international health, is an interdisciplinary program for mid-career health professionals from all over the world. It has been 33 years since its establishment, and 271 fellows from 54 countries have studied in the Takemi program so far. Many of them are actively involved on the front line of international health, occupying pivotal positions in their governments, or other roles.

The Takemi program is unique in that a university in the US and the JMA as an overseas medical association are jointly working for the program, receiving a high evaluation by the Harvard in enhancing the level of global health study. Moreover, Professor Michael Reich, the director of the program, was awarded the Order of the Rising Sun, Gold Rays with Neck Ribbon by Japan in the 2015 Spring Decoration, for his great contribution in the development of public health and international health in Japan.

The global distribution of the fellows is atypical, and there have been more fellows from developing and/or low-income countries in Africa and Asia than from the developed nations in Europe and North America. There have been 59 Japanese Takemi fellows so far, and many of them serve in leading positions in public health and international health in Japan.

I can easily imagine other Takemi fellows playing active parts in the JMAJ's subscribers' nations. Having studied in the same program, the bond of the Takemi fellows is strong and goes beyond national boundaries and time. They have, and they will, significantly contribute to their home countries by improving health standards of the people, and by developing, maintaining and enhancing their healthcare systems.

I expect Takemi fellows in each country to play even more active roles on the stage of international health as a valued human resource.

Yuji NOTO, Manager, International Affairs Division, Japan Medical Association; Managing Editor, JMAJ (ynoto@po.med.or.jp).

Principles of Medical Ethics

Japan Medical Association

The mission of medical science and health care is to cure diseases, to maintain and promote the health of the people; and based on an awareness of the importance of this mission, the physician should serve society with a basic love for humanity.

1. The physician should strive to achieve a lifelong dedication to continuing education, to keep abreast of medical knowledge and technology, and to support its progress and development.

2. The physician should be aware of the dignity and responsibility of his/her occupation and strive to enhance his/her cultural refinement, education, and integrity.

3. The physician should respect the individuality of his/her patients, treat them with compassion, provide full explanations of all medical treatment, and endeavor to earn the trust of the patient.

4. The physician should maintain respect for his/her fellow physician, cooperate with medical care personnel and serve the cause of medical care to the best of his/her abilities.

5. The physician should respect the spirit of public service that characterizes health care, contribute to the development of society while abiding by legal standards and establishing legal order.

6. The physician will not engage in medical activities for profit-making motives.