

Three Challenges in Advanced Medicine^{*1}

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Abstract

Advanced medicine has been attracting rising attention in Japan since Professor Shinya Yamanaka won the 2012 Nobel Prize in Physiology or Medicine. This short paper presents, along with some speculations, three challenges related to the development of highly advanced medicine, including regenerative medicine.

First, there is the problem of defining the bounds and limits of advanced medicine. We have to face the fundamental question of how far medical care should go. There are some people who think of regenerative medicine as a means to *immortality*, while there are others who think that advanced medicine will enable them to transcend their innate abilities and become a *better person*. The core of advanced medicine has been aimed at saving people who are already suffering from incurable diseases or disabilities, but the existence of collateral issues such as these must not be forgotten.

Second, advanced medical technology is necessarily accompanied by the issue of medical information. A type of data analysis called “big data” is already being used in a variety of situations, but the Act on the Protection of Personal Information is, on the one hand, inadequate for dealing with this and, on the other hand, could hinder social and medical reform and innovation. Taking into account the progress of advanced medicine, we should be ready for discussion about the new laws desirable and appropriate for the new health information area in particular.

Third, there is the choice of approaches to advance new medical technology: which would be better, relying on medical ethics or on law-based regulations; or in other words, should we use more guidelines established by the medical profession or administrative agencies rather than legislation enacted by Parliament? The Ministry of Health, Labour and Welfare is said to have already established a policy of enacting ex-ante regulations with penal provisions for regenerative medicine, begging the question of whether that is really a good measure in the context of advanced medicine. If inappropriately enacted, it might function as a disincentive to the development of regenerative medicine.

Key words Regenerative medicine, Neuroscience, Legal costs, Medical information, Medical ethics

The Four Principles and Three Objectives of Bioethics

At present I teach two classes called “Health Law” and “Bioethics and the Law” in the Graduate School of Law and the Faculty of Law at the University of Tokyo. Class participants are future lawyers and future graduates of the Faculty of Law. Over my years of teaching, I myself have learned a number of things in these classes. Most importantly, I have become used to apply-

ing some basic devices or concepts to approach difficult bioethical or medical issues.

Among them are the so-called Four Basic Principles of Bioethics. These originated in the US in 1970s, and since then have become well-known and are now used in nearly all countries. Anyone with an interest in this field knows these four principles of bioethics: non-maleficence (“do no harm”), beneficence, autonomy, and justice.

Other devices for thinking of health law matters are the basic objectives of health law taught

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in American law schools. There are three basic objectives: access, quality, and cost of health care. The idea is for the law and lawyers to help attain these objectives appropriately within the context of medical services. In my classes we use the concepts of these four principles and three objectives as tools for thinking about various problems in today's world. Needless to say, there is no point in just memorizing these four principles and three objectives; the question is whether one can put them to use skillfully. However, since, for instance, access, quality, and cost are all modified by the limiting phrase "appropriate and sustainable"—both terms that are very ambiguous and hard to define—the practice of application is quite difficult.

Hopes for and Three Challenges in Advanced Medicine

The same way of thinking can be applied to the hopes and challenges presented by advanced medicine. Putting regenerative medicine or gene therapy to practical use may provide safer medical care than conventional medicine by offering more effective diagnoses and treatments. It may enable the creation of drugs with fewer adverse reactions, which, in terms of the four basic principles of bioethics, corresponds to "do no harm." This would be a truly welcome beneficence for the patient; it would bring about a better condition. In addition, the new treatments for diseases that conventionally could not be healed completely would provide more access for patients with diseases that were previously untreatable.

Talking about the fourth of the four basic bioethical principles, which is justice, reducing difficult problems faced by distributive justice has been quite challenging. New therapies, however, might be helpful in resolving this dilemma. For instance, there are serious concerns about the supply of blood for emergency health care in Japan. If an inexhaustible supply of blood could be made possible by regenerative medicine, then there would no longer be a need to seriously think about the justice-related question of who should be given preference for blood. The new and advanced medicine may also contribute to the reduction of medical costs. For example, there are 300,000 dialysis patients in Japan, and 1.3 trillion yen is spent on treating those patients each year. If we could make complete kidneys

and those people could work as normal, then that 1.3 trillion yen could be put to use somewhere else. In that way, it would be possible to reduce medical costs.

There are really many diseases for which positive effects are expected from regenerative medicine, though many of them affect only a very few people. Nowadays, the number of patients who are suffering from Alzheimer's disease is on the rise. Advanced medicine is expected to offer benefits to many patients suffering from various other conditions, including those suffering from heart attacks, strokes, or diabetes. Very recently doctors performed transplants using eye cells in the first clinical study of its kind on the cornea, raising expectations further. An acquaintance of mine recently died from Parkinson's disease; now, the possibility of people with spinal damage or Parkinson's disease being cured has emerged.

However, that bright prospect comes with a number of challenges regarding technical and safety issues. Today I will speak about three of these challenges. First, we face the fundamental question of where does the scope of medical care end? State-of-the-art medicine really is on the cutting edge, and at least some people seriously fear that some aspects of advanced medicine have already exceeded the conventional concept of medicine. By making use of highly advanced medicine, may we hope for something beyond medicine? This issue brings with it the basic issue of what medicine is or should be.

Second, in the case of genetic-related techniques, in particular, medical scientists make use of genetic information, which is ultimately personal information. Japan now has a law on this issue, the Personal Information Protection Act of 2003, but this law is not appropriate for dealing with health issues in many cases. On various occasions, medical scientists have found it to be a hard burden and hurdle obstructing the advancement of medical innovation. We need reform of the law, but since health information is a so-called sensitive type of personal information, reform of the law would be a great and difficult challenge.

Third, while I just said that we need law reform, whether we should depend upon law in this area may itself be a basic issue for debate. Law is a product of parliament, and hard to amend in general terms. Since I teach in a faculty

of law, when the law is involved, I always ask what form of regulations there should be. Currently in many areas, not the form of law referred to as “hard law,” but soft law—such as guidelines and principled policy established by professional organizations or governmental agencies—are actually functioning well. It is a good, basic question to ask whether we should stick to laws or instead use other types of regulations in advanced medicine.

There are at least three serious problems we encounter here. But, before I discuss these three challenges, I would like to explain the fundamental background against which advanced medicine would be promoted; in other words, the nature of Japanese society, which can be called a high cost society.

Japanese Society: Where costs are high

A little while ago I mentioned the importance of “access, quality, and cost,” for the purpose of health law. In the realm of medical problems as well, “at any cost” is generally not acceptable in any field. Personally, I feel that within Japanese society the budget should be allocated so as to enable more investment in the field of medicine. Others would, however, point out that money is needed elsewhere, whether in education or whatever, and recently there has been opposition among many politicians in Japan. Therefore, maybe we must make do with “reasonable cost” in the health care sphere. However—and this is just my opinion—in general terms what is considered “reasonable cost” is very high in Japan. Put the other way around, there is little awareness of cost in public discussions in Japan.

Take, for example, the pitcher Shigetoshi Hasegawa, who had a win-loss record of 45-43 in Major League Baseball. He even played for a time with Ichiro Suzuki for the Seattle Mariners. He is retired now, but he is a man who left a considerable record behind. Wondering how he would do in the US, there was a TV program in Japan that followed his whole career in the US. When he left for the US he sold his house in Japan, packed everything up and moved with his whole family. He went without looking back, as if he would stay in America permanently. The first team he was on in the US was the Anaheim Angels in California. One thing that is indispens-

able for living in California—well, not just California—is a car. So, the TV program starts off with Hasegawa buying a car. What happens? Well, obviously he buys a car. He goes to a car dealer, purchases a car, and starts driving right away.

Is that kind of thing possible in Japan? I used to drive in the US and I drive in Japan. In Japan, even if you go to a car dealer, hand over the cash and buy a car, either new or used, can you just drive it away like that? Absolutely not. In some cases you may have to wait for nearly a month. But Hasegawa needed a car right away, and in California he really could go and get one just like that.

In Japan, it takes time. Of course, it also takes money. At any rate the car will have to get a safety inspection before I can take possession. Then there is the motor vehicle tax payment and different kinds of insurance. In the US, there are some places where people can drive without insurance (whether that is good or not is a separate issue). Anyway, in Japan you also have to go and get certification that you have a parking space; even getting a driver’s license in the first place is troublesome. Sure, you could just go and try to take the test, but it is not likely that you would pass. The way to do it in Japan is go to a driving school, shell out several hundred thousand yen (at least 3,000 dollars), spend a few months studying, and then get your license. In addition, every two or three years, you have to have your car inspected and examined completely and you also have to renew your license. At the license renewal site, they make you watch a DVD or video for about an hour explaining, “This or that kind of driving is dangerous,” and for that you have to shell out more than 6,000 yen (60 dollars for that hour). An American would not stand for it. Why in the world does this cost 6,000 yen? It was a little while ago now, but I remember getting a license in the US for \$10. There are even some states where you do not need a safety inspection and do not have to renew your license.

When you experience that and then move back to Japan, just having a car is really an enormous hassle (of course, all the rigmarole is justified by the importance of motor vehicle safety). I really understand why young people do not have cars these days in Japan. Of course, all this does not mean that I speed like I’m driving on the autobahn in Europe. Anyway, today’s

talk is not about cars, so I will bring this subject to an end here. It is simply necessary to note that Japanese society requires more costs to do something new than in some countries, and that those costs may include legal costs.

America: Where legal costs are allegedly high

There are two kinds of legal costs: the after-the-fact kind and the before-the-fact kind. After-the-fact legal costs refer to the risk of being sued when you have done something or being ordered to pay damages after being sued. Before-the-fact legal costs are the money spent to avoid being sued and to comply with regulations. There are many types of regulations that must be adhered to, so here we are talking about compliance and risk management.

Returning to the topic of cars again, it was the 1980s when I was living in the US, and at that time America was criticizing Japan over its automobile industry. Japanese cars had an overwhelmingly better reputation than their American rivals. They were inexpensive and did not break down, and so GM, Ford, and the other American automakers were angry, which created discord between the two countries. One of the claims by the American side was that legal costs were too low in Japan. In the US, legal costs were extremely high. There was the risk of being sued if some kind of accident occurred. Strict liability in tort on product liability was popular. An auto company also would be subject to no-fault liability in the form of product liability. Insurance for that purpose was skyrocketing. In contrast, there was nothing like that in Japan, and so the claim was one of unfair competition between the US and Japan.

Accordingly, in 1994 Japan created the Product Liability Act, which set the requirement for liability as a defect in the product instead of negligence on the part of the manufacturer.¹ Thus Japan created a law that would make it easier to pursue liability for damages. It was clear to all of us that the American criticism I just mentioned was behind this development. The main purpose was not just for the benefit of Japanese consumers. In other words, Japan had put its legal costs and legal risks on an equal footing with US to engage in fair competition.

Legal Costs in Medicine and Medical Innovation

Now then, what is going on with medical care in the US these days? A recently published paper deserves our attention. The title is “The Receding Tide of Medical Malpractice Litigation” And it was published on January 27, 2013. The paper is a surprising read.² Basically, medical malpractice lawsuits have been steadily declining in the United States for the last twenty years. Based on convincing data, “the rate of paid claims per physician has been dropping steadily for 20 years and in 2012 is less than half the 1992 level.” That is the situation of litigation concerning medical malpractice. Lawsuit rates have also been declining. So, the question is why?

According to this paper, the first reason is that many states in America have adopted a system that makes it harder to bring a case to court. This has been achieved through the so called “tort reform” designed to make medical malpractice litigation more difficult, such as putting a cap on damages, requiring review by a panel of experts before a lawsuit is filed, and reducing the time period of the statute of limitations. The fact that the rate of paid claims has dropped to less than half is really significant.

It has also been made clearly difficult in the US to bring product liability suits relating to medical care. In the first place, tort claims cannot be brought in the US for products that have been approved by the federal government, which is, in this case, means the FDA (Food and Drug Administration). You cannot bring a suit claiming, “Hey, there is a defect in this medical device.” It is also very difficult to file a tort claim concerning pharmaceuticals, since the FDA approves them, too. Therefore, medical care in America as a whole has changed enormously in the past 20 years, heading in the direction of lower legal costs.

Behind this phenomenon is the fundamental question, “Does using these kinds of legal actions and laws make medical care better?” Some people in US doubt the efficacy and merits of litigation in this sense. In addition, there is no doubt of political influence behind the scenes. I am sure that there was political influence from the American Medical Association, the insurance industry, and/or the Republican Party. However, from an academic point of view, the more impor-

tant question is whether legal action has really made health care better. Did health care in the US improve with the steady increase in medical malpractice litigation? Does the evidence bear that out? The success of tort reform shows at least partially that many people could not believe in it.

As for the compensation of victims, criticism against tort litigation has been serious in the United States. The question is whether sufficient relief is provided for victims through the courts, and the literature and research show that they are clearly under-compensated. You can get only partial compensation, despite sustaining so much injury. If this is the case, we should seriously consider methods other than litigation to ensure medical safety and compensate victims.

Let us come back and think about how things are in Japan with regard to tort law. Americans may say, "But medical malpractice doesn't amount to much in Japan, right?" The answer would be, "Yes. We have a considerably smaller number of lawsuits in the medical malpractice field compared with the US situation." Nevertheless, I have to emphasize how high the legal costs are for medical care in Japan.

First of all, we have a system of no fault compensation for adverse reactions to drugs, another compensation system for adverse reactions to vaccines, and more recently, the no-fault obstetric compensation for children with delivery-related disabilities (established in 2009). Lawyers call these administrative compensation systems, and Japan does have a considerably developed system of compensation in the medical field. However, lawsuits can invariably be brought to the court in parallel to these systems. As a result, Japan does have a certain number of drug-induced suffering cases—so called medical malpractice lawsuits. That risk is always present and deeply felt among physicians and drug companies. In the United States, in contrast, you can usually only choose one of either an administrative compensation scheme or litigation. Both are supported by the Japanese Government. It may be better to concentrate public resources into just one of these, but in Japan many lawyers and members of the general public believe in the right to bring lawsuits as a fundamental right. In addition, liability can be sought against the national government in our country; that is not the case in the United States. Our government takes responsibility. Cer-

tainly this is admirable, but what it boils down to is that when we say the government takes responsibility, it means our tax money is to be paid. In other words, the bill is covered with public funds; responsibility is dispersed throughout society as a whole.

In the same way, there are two side-by-side redress systems for medical devices, pharmaceuticals, and product liability, and furthermore, the government is always subject to lawsuits. Our system is built to an extreme degree on the basic idea of responsibility and liability in law, creating a high legal risk that goes, in some cases, so far as to question criminal responsibility, which is what surprises Americans. We are not talking about a doctor who killed a patient intentionally, but human or system errors in medical care. In Japan, there is the possibility of criminal responsibility and/or civil liability in medical accident cases.

As a matter of fact, in health care as well, legal and administrative costs are too high, just like with obtaining a car, as I mentioned earlier. Our truly serious problem is whether or not these costs are directly connected to patient safety. Do we have true peace of mind under such a system? Can Japan naively say to other countries, "We have developed a legal system for patient safety. You should learn from us"? Things are not, after all, going that way.

One problem that has been pointed out so far is that because Japan has built an overly burdensome system, the development of new drugs and new medical devices is falling far behind other advanced countries. Japanese pharmaceutical companies tend to do clinical trials overseas because they cannot be efficiently conducted in Japan; some drugs that are used overseas cannot be used in Japan; and so on. Moreover, legal intervention—particularly the fear of criminal prosecution—has had an atrophying effect upon medical professionals. Surgeons and other physicians in other high-risk specialties are decreasing in number. Have we ended up creating a situation in which people cannot feel peace of mind with health care services, which is the opposite of what was intended?

I am truly worried that these factors in Japan will negatively influence innovation in the area of advanced medicine. If there are overly strong ex-ante regulations and if the system for pursuing ex-post facto legal responsibility is strong, I am afraid that advanced medicine will not keep

on advancing steadily. The government has said that it will make advanced medicine, and regenerative medicine in particular, a main pillar of its growth strategy, but is that really possible? Can Japan truly be competitive against the United States or EU countries? Regarding the comparison with the United States, I feel that we have created a situation that is the exact opposite of the 1980s, one in which we can feel like saying, just as America did before, “How can we have fair competition if your country does not make systems that are just as severe as those in Japan?” Maybe, the answer would be: “That is your decision. Japan did this, and other countries do not need to follow suit.”

Three Challenges to Realizing the Hopes for Advanced Medicine

Where does the scope of medical care end?

Now I finally return to the main subject of my talk, which are the three challenges to pursuing advanced medicine. Regenerative medicine and neuroscience, which has recently received tremendous attention, are areas in which progress is highly anticipated by many people because of their goals of saving people who have suffered from hard-to-cure illnesses. Naturally, there is no problem in justifying this kind of new medical research this way. However, the advancement of this new medicine is accompanied by some problems. Since it will enable the rejuvenation of cells and organs, regeneration would make life expectancy longer and longer. However, is it always desirable or acceptable to keep extending life expectancy in Japanese society? We could safely say that just prolonging life is not always good—at least, not the main aim of medicine—in an aging society like Japan.

While it is not an example of regenerative medicine, the issue of neuro-enhancement came up in some books and papers I read recently. This is a slightly different kind of advanced medicine from regenerative medicine, but as neuroscience advances further and further, many things will become possible. A German scholar, for instance, writes that neuro-enhancement is already possible and brings with it new kinds of issues, such as the following example.

He put this question on an examination: “A is a Faculty of Law student. His grades are very bad. At A’s request, a doctor gives him psy-

chotropic drug M used to treat hypersomnia (excessive sleep disease) and also antidepressant F. The result is instantaneous. Thereafter A is able to study for 15 hours a day without feeling tired or bored. He passes his exams with flying colors.” The question was then, if there are any problems with this scenario from the perspective of bioethics and the law, what are they?

A number of problems can be pointed out. First of all, A can not be said to have a disease. It would be outrageous to say everyone with poor grades is sick! What would happen if such people were prescribed drugs and they developed an adverse reaction? The basic principle is that medical care exists in the first place to cure disease and ease suffering. Also, the use of drugs based on Japan’s universal health insurance coverage to improve grades would, from a legal perspective, be illegal and would go against distributive justice in terms of the principles of bioethics mentioned earlier.

Another answer, one that anyone might think of right away, is that if we were talking about the world of sports, this would be a case of doping in every way. In other words, it is really unfair. Then there is the argument of the slippery slope; it is highly unlikely that only A will seek a drug boost. Once the word gets out, B and C and D and everyone else will use them, too. And what do you think will happen when people try to improve their own grades relative to others? They will use more and more drugs. If 15 hours of study is not enough, then it is likely to increase to 20 hours. If 20 hours is not enough, then the next stage would be 36 hours a day! Well, I’m just kidding about that. Since there are only 24 hours in a day, I guess that is the limit. At any rate, if that were to happen, would it be okay?

The most serious aspect, however, is that this medicinal agent is having a direct effect on A’s brain. That raises the question: has it altered the personality of the person called A? There is also a problem with cosmetic surgery, but if one makes the distinction, at least cosmetic surgery only affects the outside of human beings. The German scholar continues to pose all kinds of arguments, such as how about creating the same effect through electromagnetic stimulation of the brain, not just with drugs that affect the brain?

I think there is a very difficult challenge here in how to differentiate between intervention for enhancement such as this and intervention as

medical care for someone with some kind of nerve damage. And so, up until what point is medical intervention acceptable? And who decides? What is medicine in the first place? That is the first point to note with regard to the advancement of medicine. With this issue there is always this problem of distributive justice. If we focus all our attention on just advanced medicine, something else is going to be neglected in the limited budget of our government. We should not forget about the issue of the distribution of limited resources.

Big data and the protection of personal information

The second challenge is big data and the protection of personal information.³ A law dealing with personal information protection was enacted in 2003 and put into effect in April 2005. We now have eight years of experience with this Act. I hear that the Health Ministry may enact a Medical Information Specifics Law in the near future. Within the Ministry, there has been discussion about this possible enactment, but it is not yet widely known. I think the public and society should debate it more widely and openly. That is one reason I mention it.

Personally, I am in the anti-personal information protection camp because the harmful effects of the Act mentioned above, especially in medical settings, are now all too obvious. Take the Amagasaki rail crash of 2005, for example. More than one hundred passengers were killed. Hundreds of people with minor or severe injuries, were taken to various hospitals nearby. A great number of people were transported to many different hospitals. Naturally a number of calls and visits by people concerned about the safety of their relatives and friends were subsequently made to these hospitals. Surprisingly enough, there were a considerable number of hospitals that said they could not give out any information when family members inquired. They said, “We cannot provide information because of the Act on the Protection of Personal Information.” What a stupid reply! Later, the Ministry of Health, Labour and Welfare clearly said that such a response was a mistake or misinterpretation of the Act, but the point is that most people thought that way with regard to this Act.

Another example is major earthquakes. In the 2011 Great East Japan Earthquake—and I

think it was the same during the earthquake in Kobe in 1995—the Japanese system regarding medical information was clearly deficient. No one knew where patients were. Where exactly are the patients on artificial respirators right now? They need to be found immediately and assisted. It was a life threatening situation for those people. The same goes for dialysis patients and others who could not run away to a safer place on their own. The Personal Information Protection Act has become a hurdle and wall for sharing such information.

Or consider that data on patients with cancer, which is the Number 1 disease causing death among Japanese, are hard to collect due to the influence of the Act. After the Act was established in 2003, some hospitals stopped providing data to those trying to gather information for research. Their claim—or excuse—was simple: it is personal information. The same is true with outbreaks of new infectious disease. Of course, with infectious diseases there are also factors such as isolation and enforcement measures, but it is certain at least that the Act would have had bad effects on Japanese society.

Let me talk about personal information matters from a different perspective. There are two main systems for dealing with personal information: the EU system and the American system. In the EU, they created the catchphrase “data privacy” and protect any and every kind of data as long as it is personal information. Under the American system, a different approach has been taken. Not personal data in general, but more specific data are subject to legislation there. If I write a letter of recommendation, for example, that is information related to education, and so the student for whom I wrote the letter of reference can read it, because it is his or her own information. There is a law about educational information that gives the student the right to see just how many derogatory or splendid remarks I wrote or in what way I recommended him or her.

In the US, there is a medical information law called HIPPA, the Health Information Portability and Accountability Act of 1996. In 2000, the Department of Health and Social Services established a regulation that is usually called the “HIPPA Privacy Rules.” Another law was enacted relating to credit information. This law protects such information concerning a person’s

credit history. Thus, the American system is referred to as sectoral.

Japanese law has been influenced by the European system. In 2003, as I said before, Japan enacted the Act on the Protection of Personal Information. Based on the European system, the Act was supposed to conform to EU standards. The ridiculous thing is that the EU has told Japan that this law is not in conformity with its standards. It is truly unbelievable. I mean, if you are going to make a law that conforms to the European model, well then make a law that will be praised by Europe!

Although I think what he wrote is wrong and misleading, a certain Australian scholar published a paper in English in which he said Japan is the worst in terms of personal data protection, even when compared to other Asian countries. This is staggeringly different from the Japanese perspective. We are very sensitive to personal information, to the point of overreacting. But this Australian doesn't understand this because he is simply reading law in books and writing on that basis. Since he writes in English, however, people all over the world might read this paper, and be misled into thinking that Japan is awful regarding data privacy. I really think this is sad and ridiculous.

Last year in the EU a rule calling for further strengthening of data protection was proposed. The main aim of this proposal is to strengthen the protection of personal information. The fact is that, even within the EU, personal information data should be used more broadly so that the EU may function well as a single market. If you want to use personal information more freely in the EU market, then, the proposal argues, it needs to be given more protection under EU uniform regulations. Nowadays collections of information are sometimes called big data. Last year, big data came into vogue even in Japan. The Ministry of Economy, Trade and Industry, the Ministry of Internal Affairs and Communications, the Cabinet Office, and other government agencies in Japan competitively created committees or investigative commissions on big data, resulting in various reports.

Big data allows the extraction of data according to the individual characteristics of the target (**Table 1**). A typical example is the company Amazon. I buy books from Amazon over the Internet, and they send me ads all the time, prac-

Table 1 Big data and its use in medical care

Big data does not merely mean a large amount of data. For example, data sets for obtaining new findings and discoveries have the following characteristics:

- 1) High resolution (data can be extracted according to the individual characteristics of the target);
- 2) High frequency (data can be analyzed practically in real time); and
- 3) Diverse and unstructured (links can be made between many kinds of data).

tically every day. They are really considerate: “Mr. Higuchi, other people who have bought the books you have also bought these kinds of books.” It is not that bad, because they sometimes introduce me to good books. At any rate, the point is that they instantaneously know that this kind of person buys these types of books, and the recommendations come up right away. Analysis is possible virtually in real time.

For instance, I often go to the convenience store in front of my university to buy *onigiri* (rice balls). So, the store knows that a 61-year old man—well, maybe not so detailed—that old men in their sixties come to buy this kind of *onigiri*. That then affects the store's purchase of stock for the next day. This kind of thing is already happening. It is just one example of big data. It enables all kinds of unexpected connections to be seen in information, and that knowledge can be used in business and other areas. Some people think that is a really great thing, but other people think it is scary.

The use of big data in medicine

I recently read an academic article which taught me that the use of big data is playing a leading role in medicine in the United States.

One example cited was a drug called Vioxx, which is an analgesic for arthritis. The following story is very well known in the world of medicine, so you may know about it. Anyway, in the beginning the drug sold really well because it is very good at relieving pain. However, there are a certain number of people who die from heart attacks every year. I do not know myself, but perhaps someone thought that maybe there is an association between the two. When a health care provider organization called Kaiser Permanente analyzed a large amount of data, sure enough there was an association. In the article it

said that, although it had been thought up until that point that there were no side effects, in fact the drug was the cause of as many as 27,000 deaths from heart attacks. It wasn't until this revelation that some kind of revision was made for the first time in the sales method for Vioxx. Of course, this is a really good thing, because the connection to heart attacks wasn't known in the beginning.

My second example is flu forecasts on Google. I don't understand how this works exactly, but I have a smart phone, and Google sends information updates to it. It's the same as or similar to weather news: "It's cloudy over your house now," or "It has started to hail." A great number of users sends current data through their smart phones to a weather news company. It is real-time and current information. The company then collects and analyzes the data instantly and sends the results simultaneously to companies in various fields that need weather information. Likewise, Google collects data on all these people who have the flu or see others with the flu, and it sends updates to medical institutions. They can then tell instantly that the situation is like this or that in this area but not in an area a little way away. They know what is happening in real time. They know that this type of flu is going around in this area but there are still not many flue patients in that area over there; however, the infection is spreading quickly in such and such a way. Thus, while they may not be able to completely call a pandemic based on this information, apparently it helps speed up medical and administrative responses.

One more example: they say that in the US a pill case has been developed to stop people from forgetting to take their medicine. I'm just guessing about this, but what might happen is that if you forgot to take your pills as prescribed by physicians, the case probably contacts someone somewhere, triggering an alarm, which in turn causes an email or other warning to be sent to you. So, I guess this pill case is constructed in such a way that it knows whether you forgot to take your pills. If a great amount of such information is collected, then an analysis can be carried out in advance about the kinds of patients who need this kind of warning. Well, I suppose it is good that big data can be put to practical use, since it is true and could enable advanced medical care if, for instance, a system that monitors

the status of use of inhalers for asthma patients could be developed to see how patients behave in everyday life.

Of course, monitoring the status of patients in real time raises the question: doesn't this conflict with the protection of personal information? But is there any problem with conflict in the example just given? Should not Japan—which has already become a highly aged society—now construct systems that protect the elderly through this kind of medical and nursing care and other sharing of information? And isn't there a greater need now than ever to make use of information to eliminate waste in medical care, in order to maintain social security, and to provide high quality medical care inexpensively?

The “right to be forgotten” and the “right to not be forgotten”

Another catch word in the EU's proposed regulation I mentioned a little while ago is the “right to be forgotten.” Take for example someone who, in youthful indiscretion, posts pictures and videos of his rowdy days on the Internet. He may think at that time that he looks cool, but these images will become embarrassing in his thirties or forties. He will therefore want to delete those images, but that is not so easy once something has been put onto the Internet. The EU is trying to do something about this.

That is where the “right to be forgotten” comes in. Can everything be deleted, even down to things that other people posted or copied without permission? Is that even technologically possible? Then there is the issue that this is a kind of freedom of expression for other people. Right now this regulation is just a proposal, so I don't know how things will turn out. However, perhaps because I have passed 60 years of age and am entering the generation that is quickly being forgotten, even on campus, it has occurred to me that perhaps the “right to not be forgotten” is even more important in our country.

There was a recent article in the *Asahi Shimbun* newspaper about a hotline that receives 30,000 calls a day from people and many callers could not reach it because there are so many calls. The hotline was set up to provide telephone consultation for survivors of the Great East Japan Earthquake in Iwate, Miyagi, and Fukushima Prefectures, but only three out of every 100 calls get through. Clearly, the callers want to communicate with someone; they want to connect

with someone. They want to make an information link.

Another news article said that nowadays more than 30,000 people kill themselves every year, ten times more than the number of people killed by others. Accordingly, local authorities have been cooperating with outside institutions and hospitals to combat suicide and in 2012 the annual number of suicides finally dropped below 30,000 for the first time in 15 years. What do you think this suggests? Information about people who seem like they might commit suicide is being shared in some form or other. And the fact that some kind of measures were taken seems to have had a slight effect. This is a second example of the necessity of sharing information rather than preventing the sharing of information in the name of privacy protection.

A third example is more scary for our society. The National Institute of Population and Social Security Research has published a prediction that the number of single-person households, which is already one in three, will increase as the population keeps aging, reaching 40% in 2035. So many people will live all alone! This means that, if people living alone cannot or do not share personal information with others, and if they stay indoors, then they could be easily forgotten by others.

In Japanese, we now have a new word that means “solitary death,” pointing to the challenge of how to prevent this. The typical situation is this: an old person living alone becomes weaker and weaker and finally dies, but it is only found several months later. In such cases, it is better if we do not have the “right to be forgotten.” Even without that right, people living alone are in danger of being forgotten. Actually, I think the “right to not be forgotten,” the linkage and sharing of personal information, will be important for such people.

Some local governments are already starting to build networks to look after people. This needs to be even more systematized and done properly. Technologically, it is really simple. With cell phones, smartphones, tablets, and other devices it is nowadays possible and easy to create links, and it does not have to cost that much money. At the same time, the people targeted by such a system are also usually patients, and the system would be beneficial for not only each patient, but also for the general public. One simple sce-

nario is that if the data for people who take their medication as prescribed and those who forget to take it are different, the effect of those drugs may become clear later down the road. The system could be used for such purposes as well.

The issue of privacy and protection of personal information

The issue of privacy and protection of personal information has been raised as one of the legal issues connected to human stem cells. Stem cell research comprises a major part of advanced medicine, and so, when the Medical Information Specifics Law is enacted in the future, we should regard this as an opportunity we have been given to reconsider how medical information ought to be, including the issue of regenerative medicine.

Exactly how far does information held by a cell—genetic information—have to be protected? From the perspective of public health, any symptoms from genetic factors have to be pursued. How far will traceability be ensured? And, how much of the information obtained should be returned to the cell provider? Naturally, these are issues that have to be addressed. The challenge of creating an appropriate balance between protecting personal or genetic information and broadening the use of such information to improve public health is enormously difficult. However, I feel that we should think about somehow providing protection of personal or genetic information within a reasonable scope without over-protecting it, and make use of it as data for improving public health. If you know the prevalence of a certain disease and know what kinds of diagnoses and treatments are being carried out for that disease, you can improve the EBM (evidence based medicine) for it, or you can share and secure information about the locations of patients with certain medical conditions after a major disaster and whether they are waiting for help. You can also see if approved drugs are actually being used and whether they are achieving the expected effects.

With regard to the last point, something that I was surprised to hear was that France has actually built and is using a medical records data system that covers the entire populace: 60 million people, including newborn babies.

A system like that could be useful in preventing the recurrence of medical accidents by analyzing the fields and procedures as well as the contexts in which they occur. Also, if a certain

patient is being treated at more than one medical institution, repetition of the same tests could be avoided. I think these would be good uses of such a system.

If we have the chance to enact the Medical Information Specifics Law, or Special Law, it would be a good opportunity to correct the failures of the Act on the Protection of Personal Information within the context of health care. Also, the protection of personal information must not be a barrier to the appropriate promotion of advanced medicine. On the contrary, if the use of personal information were the default, then in the case of medical care it would be only natural for there to be a desire to specifically protect personal information. No one denies that some measures to protect personal information need to be considered, but we should not repeat the same mistakes we made with regard to the Act on the Protection of Personal Information. That is the second challenge for us with regard to law and medicine, and especially highly advanced medicine.

The form of advanced medicine regulations

The third challenge is the form regulations ought to take. Many guidelines have been issued thus far in the health law area. Should we be satisfied with regulations in the form of guidelines, or should laws be enacted? Then again, rather than laws, should regulations take the form of medical ethics?

With regard to stem cell research, the Japanese government has imposed heavy regulations in the form of guidelines. Embryonic stem cell research is under strict restraints without any decision making by Parliament. However, the Asahi Shimbun newspaper recently carried an article entitled “MHLW (Ministry of Health, Labour and Welfare) Proposes Legislation with Teeth for iPS Regenerative Medicine Approval System.”⁴ They are now finally trying to make a law. As was also mentioned in the article, sham regenerative medicine and other procedures dressed in the guise of regenerative medicine have apparently been appearing one after the other. Some kind of regulation should be implemented, I agree, since these procedures can be extremely dangerous. If laws are not formulated reasonably, however, legislation could turn into over-regulation, and I worry that that could hold back much-awaited research and

clinical applications.

In 1970, Professor Koichi Bai, who was Japan's foremost pioneer in medicine and the law, came out with a book, published by Iwanami Shoten (Publishing Company) in which he wrote, “How the law establishes the duty of the physician is a perpetual issue.” What this means is that there is simply no justification for the law to provide for anything and everything when it comes to medical care. Most issues should be left to medical ethics and only a very few should be governed by positive law.

Some 40 years have passed since then. During this time, the trend regarding the regulation of medical care has in fact been aimed at increasing laws and regulations rather than improving medical ethics. I call it the “legalizing of medical care.” Even though it has taken the form of guidelines, the effectiveness has still been apparent. If academic researchers or physicians do not comply with these guidelines, then they will automatically lose their eligibility to apply for government research grants, which are indispensable for scientific research in Japan. I think people who conduct research will understand this right away. You will get yourself into a real mess if you do not actually follow the guidelines (**Table 2**).

Why is that? Does it mean that there is distrust of medical ethics? A system for properly providing education on medical ethics in medical schools and lifelong training has not been developed in Japan, and, although professional organizations—including, of course the Japan Medical Association—provide cooperation, it is not always the case that a system has been prepared for autonomously establishing rules within the professional circle.

There are a number of ways to legalize medical practices, and guidelines have been used relatively frequently. Even so, the character of guidelines differs considerably depending on whether they are so-called government regulations issued by the Ministry of Education, Culture, Sports, Science and Technology or the Ministry of Health, Labour and Welfare—that is, top-down guidelines—or whether they are issued by professional groups, societies, or other organizations.

In the case of hard law, usually everyone in Japan thinks that penal provisions have to be added to the Act. This stereotypical thinking is too simple and troublesome. As a matter of

Table 2 Legalizing of medical care

<p>1. Weakening of medical ethics; distrust of medical ethics</p> <p>(1) A system for properly providing education on medical ethics in medical schools and lifelong training has not been developed.</p> <p>(2) Professional organizations have not developed systems for autonomously establishing rules.</p> <p>2. Many types of legalizing</p> <p>(1) Soft law (guidelines)</p> <p>There are two kinds of soft law: those issued by professional organizations and those issued by the government (Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare)</p> <p>(2) Hard law (legislation (usually including penal provisions in Japan))</p> <p>There are methods of response that do not involve penalties (e.g. the duty in Japan for physicians to provide medical care) such as administrative disposition and civil compensation, but there is a tendency to think that laws always have penal provisions. This area is also a hotbed for detective intervention into medical accidents.</p>
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fact, there are many types of regulations; there are a number of other approaches besides using penalties. However, when making laws at the national level, the default is to try and attach penal provisions, even if just for form, which would necessarily have a chilling effect on academic researchers, even with regard to appropriate research protocols.

I would like to show you one example for the division of roles between law and medical ethics. I found a question similar to the following on a practice exam for the national exam for physicians in America. Well actually, what we call a national exam in Japan is administered at the state level in the US. Anyway, it was a surprising question for me and so I use it in various presentations and other situations in the hope that it will be interesting to others.

The question has the following scenario: "A man is transported to the emergency department, but he is brain dead on arrival. An organ donation card is found sticking out of his pocket or somewhere. The medical staff start considering harvesting the organs for transplantation, but the man's family shows up and says, 'Absolutely not.' What should be done?" There are five choices: a) Remove the organs regardless; b) Wait until the patient's pulse stops and then remove the organs; c) Stop the respirator and then remove the organs; d) Request a court order to overrule the family's opposition; e) Accept the family's wishes and do not remove the organs.

In the US, self-determination is important,

and also in the eyes of the law, brain death is death. If this is a legal question, then the answer is simple, and it should be a). In law, the patient's intention is sufficient; thus the family has no rights whatsoever from a legal perspective. The organs should be harvested for transplantation. However, that is the incorrect answer on the physician licensure exam. The correct answer is "e)," and physicians have to accept the family's wishes and not remove the organs, which is the position to take from the perspective of medical ethics. Doctors cannot go so far as to harvest organs for transplantation over the protests of family members. They believe that even if the law allows it, ethics are separate from the law.

The same goes for end-of-life care. While there seem to be a considerable number of people in America who say they do not want any life-prolonging treatment at all, there are certainly families who ask to try everything possible, do not stop any medical procedures. In a medical setting, the doctors are not going to say, "We can not listen to you because the patient has a living will." On the contrary, these are situations in which they are going to *treat the family*. They explain to the family that "if we do everything possible, in a real sense the patient is going to stay in a state of agony. It is going to become an increasingly miserable condition." Such an explanation convinces the family, and then life-support is pulled. That could have been done right away according to the law, but the fact that it is not done is another example of the separation between the

Table 3 Summary

February 15, Discussion of Life Innovation Strategy at the Cabinet Office
 “Proposal for Special Advanced Medicine Development Zones”
 Professor Teruo Okano, Vice-president, Tokyo Women’s Medical University

Three challenges related to advanced medicine:

1. Where does the scope of medical care end?
2. Handling of medical information: big data and the protection of personal information
 Learn from the failures of the Act on the Protection of Personal Information
3. The form of regulation: laws or guidelines or medical ethics?

While these three challenges may seem unrelated at first glance, the appropriate development of advanced medicine and assurance of the protection of human rights require strategic, substantive, and flexible ideas, not conventional, rigid thinking.

law and medical ethics.

However, I seriously doubt that the same thing could happen in Japan. Physicians in this country may rely upon law and regulations more easily, emphasizing to patients’ families that the rule is this, or we should follow the law. No mention of medical ethics is necessary.

The form of regulations is naturally a problem when it comes to advanced medicine as well. The new Regenerative Medicine Act will likely require pre-approval of clinical research and application. It will keep ex-ante regulations, with penal provisions as well. Furthermore, while it is okay to threaten bad guys with penalties, the question is: is it okay to do the same thing to good people? When dealing with responses based on traditional, typically Japanese hard law—methods that are traditional for us in Japan—there is a need to also consider whether everyone is doing this internationally. There is also concern about whether such regulations will impede the development of advanced medicine, which is a concern in terms of international competition.

Of course, taking such measures is necessary for medical safety, for the safety of patients. However, have we not gotten to the point where the phrase “patient safety” has become a magic word for justifying all regulations, and maximum regulations at that? And does that not end up jeopardizing safety in some cases? Furthermore, it would be of no benefit to patients if these kinds of treatments could have become possible much sooner in Japan but were delayed due to regulations. However, in asking what kind of regulations we should have, I think we need to listen to and consider the voices of those on the medical

frontlines, the voices of patients, of medical professionals, and also of information specialists.

Advanced medicine really is advanced, and so do we need uniformity across Japan? If the law is uniform throughout Japan, then it will seem fixed in stone in peoples’ minds. However, we could have concepts like special zones where the specific laws are not applied and exemptions are allowed. Of course, that does not mean that laws should be removed or that all safety measures should be done away with. A certain level of precaution must be taken, but I think that we need to think in the future about a flexible regulatory system in which researchers can try something in a certain area for two or three years to see how it goes and then expanded it nationwide. This approach should be allowed precisely because a technique is advanced medicine. In other words, since advanced medicine is beyond our ability to predict, we should think of different approaches. We also have to keep alert to international competition and international standards. Otherwise, Japan’s researchers will end up going somewhere else. We would really be in trouble if it turned out that we could not even conduct clinical trials in Japan.

Conclusion

This morning I went to the Cabinet Office to attend an advisory meeting where I was able to listen to Professor Teruo Okano talk about life innovation strategy. Dr. Okano made a proposal about special advanced medicine development zones, and I felt very sympathetic to parts of his talk (**Table 3**). In any event, do we not

need to make regulations themselves advanced? I am not saying that being advanced is always good. After all, advanced medicine means that there are in fact big risks.

What I have talked about today is simply what I have felt as a layman looking in from the outside, as a person who does not understand the medical or scientific content at all. The three themes that I discussed may seem like three

unrelated points that I just put together. Ultimately, however, in order to achieve the goals of appropriately developing advanced medicine and ensuring the protection of human rights, I think that we need flexible ideas that are not constrained by form and that are strategic and substantive rather than thinking that is conventional and rigid. This also holds true for regulations as well as the forms laws should take.

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