



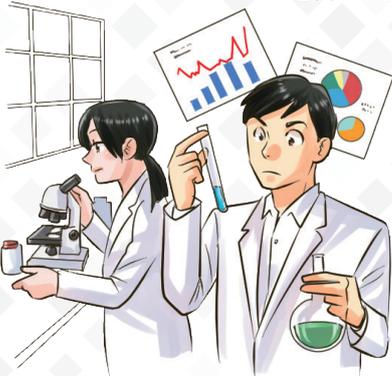
How Medical Information Is Used



For Our Future Medical Care



The Next Generation Medical Infrastructure Law has been enforced to promote medical research using big data. Learn how our medical information is used in this booklet.



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For Our Future Medical Care...

Medical progress never ceases to amaze us. We often see cases where it becomes possible to cure a disease that was incurable a mere decade ago. This progress is the result of the strenuous efforts of many healthcare professionals, medical researchers, and investigators at pharmaceutical companies around the world. Have you ever wondered how they conduct healthcare and medical research and development? Sometimes they find new chemicals, and other times they culture cells in test tubes to discover something new. However, analysis of patient medical data plays one of the most important roles. In other words, the good will of many of those fighting against disease supports progress in healthcare. The advancement of what we know as modern medicine would not have been achieved if it had not been for the good will of many patients from ten, fifty, and even a hundred years ago.

This booklet explains in a clear and simple manner how the good intentions of patients are used for future medical care without prejudicing their rights.

1 Information Technology Supporting Advanced Medical Care

Q What types of medical data are there and for what purpose are they used?



A Medical data includes the medical history of patients that is gained by physicians by asking patients questions regarding **their medical conditions**, **various tests (blood test, X-ray exam, etc.) results**, **diagnosis**, **treatment (prescription, injection, procedure, surgery, rehabilitation, etc.)**, and **results of treatment**. Doctors examine individual patient data and use it for medical treatment. At the same time, data are collected from many patients to **create comprehensive statistical data**, which can be used for improvement of medical care in general.

Q What is clinical research?



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A Clinical research **evaluates the efficacy and safety of medical care** by aggregating and analyzing the test and treatment results of many patients. Conducting a large number of clinical studies will promote **evidence-based medicine** and improve medical care provided to individual patients.

Q What kind of information is receipt information?

A The histories of medical care provided to patients are recorded on medical fee bills (receipts). In recent years, anonymized receipt information of many patients has been collected and analyzed **for the improvements of healthcare delivery systems and the quality of medical practice**.

Content of Medical Information and Purposes of Use

Health is the most important thing in our life. We all want and pursue physical and mental well-being. Any of us can get necessary medical attention at any time when we are ill or injured. **The role of medical institutions is to provide us with long-term and extensive health support** ranging from routine medical examinations and provision of advice on healthcare to specialized treatment of particular diseases.

Doctors and nurses collect a variety of information to ensure that patients receive appropriate treatment. They listen carefully to patients and include the details of diagnosis and treatment (e.g., prescription, injection, procedure, surgery, rehabilitation, etc.) in their medical records. All of those records are stored as medical information (i.e., data). In addition to numerical values, data contains documents and images.

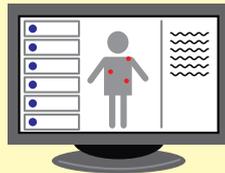
Medical information has **two main purposes of use**. The first is to be used **for**

treatment of patients, and the second is to help improve medical care. Both are aimed at restoring patients' health.

Two purposes of use of medical data

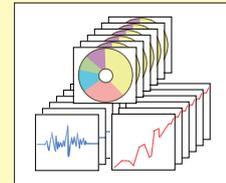
1 Treatment

Doctors make medical judgment and provide treatment based on the personal medical information of each patient.



2 Improvement of medical care

Data is collected from many patients to create statistical data for improvement of medical care and prevention of diseases.



These are also the purposes of medical care!

The data is used to treat disease and to maintain and improve health in both cases.

Medical Care is Based on a Great Deal of Research

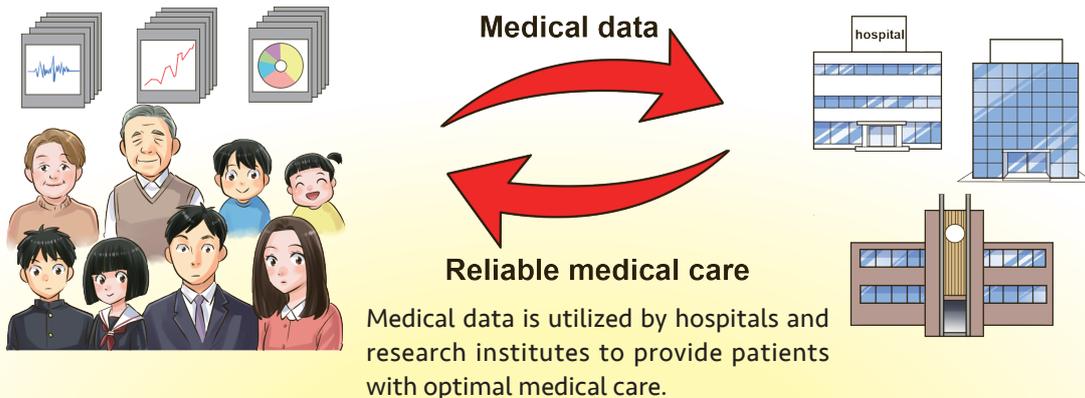
The medical care we receive in hospitals and clinics is based on the study of medicine. Medical research includes [basic research](#) and [clinical research](#).

Basic research reveals the mechanisms and functions of human cells, tissues, and genes, and [elucidates the origin of diseases](#). This type of research is mainly conducted in laboratories. Clinical studies are [conducted on people](#) in medical practice. In clinical research, data are collected from many patients to perform statistical analysis and [to obtain new evidence](#).

Even the patients suffering from the same disease have different conditions and degrees of progression. A certain type of treatment may work for some patients, but it may not be effective for others. Medicine is fraught with uncertainty. Therefore, it is important to conduct clinical research to determine what tests and treatments are most appropriate for each type of patients. [Evaluation of the effectiveness and](#)

safety of medical treatment contributes to the progress of medicine to more reliable practice.

In recent years, medicine has become complex and diversified. We have an increasing opportunity to listen to and understand the explanations about diseases provided by doctors and to decide on our own what treatment to receive. **The improvement of the quality of life (QOL)** of patients largely depends on clinical research. A number of clinical studies are conducted for the utilization of medical information and to provide the best medical treatment possible for each patient.



Data-based Healthcare Service

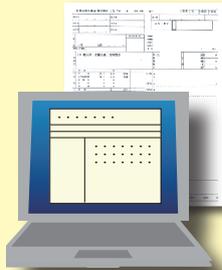
Japan applies a [universal healthcare system](#), which signifies that almost all the nation's citizens have joined public health insurance. Medical services covered by public health insurance are called insured [healthcare services](#). Most of the medical institutions in Japan offer insured healthcare services, but not all medical services are covered by public health insurance. [Certain evidence \(scientific basis\) supporting effectiveness and safety of the medical services is required](#) for services to be covered by public health insurance.

Patients pay a part of their medical expenses to receive insured healthcare services. The history of insured healthcare services is recorded as data on [medical fee bills \(receipts\)](#). Medical institutions submit those receipts to examination and payment agencies to bill them for medical expenses. Examination and payment agencies pay the medical expenses when the submitted bills are deemed appropriate.

Recently, a large volume of **anonymized receipt data** have been collected and have been used for numerous and discrete purposes. National and local governments utilize such data to understand the actual state of medical care in each region to establish an appropriate healthcare delivery system. Receipt data are also **used in clinical research**.

Utilization of medical big data

How receipt data is used



Receipt data are business data generated daily in medical institutions. In addition to their use for medical expense claims, the utilization of a large volume of anonymized receipt data contributes to the improvements of the insured healthcare service delivery system and the quality of medical care.

“Anonymization” is to make an individual unidentifiable by processing name, date of birth, health insurance number, etc.

2 System to protect the privacy of patients

Q I do not want anyone to know about my medical condition.
How is the privacy of medical information protected?



A Medical care is based on the results of medical research conducted using data on actual cases of disease and treatment. However, since physical and medical conditions are the most sensitive and important personal information, doctors and healthcare professionals have been handling such information carefully for a long time.

Nowadays, however, we have access to many medical data. Genetic testing kits for home use are available online and anyone can self-administer a simple cancer test. So far, medical information used to be handled only by healthcare professionals, but now any business entity or

individual has easy access to such information. In fact, some companies misuse such data to make money.

The Personal Information Protection Act was amended to prevent this situation. It prohibits misuse and the use of medical information of other individuals without their express permission. However, medical research and the development of medicine would be very difficult without access to medical information. **The Next Generation Medical Infrastructure Law** was enforced to permit the use of a part of the data necessary for research and development for future medical care after removing personally identifiable information. **This law protects the privacy of patients.** Those who feel uncomfortable allowing their medical data to be used can **request the suspension of use.** Please do not worry, the information will never be used without the permission of individual patients, and it will not affect the treatment provided.



Dr. Ryuichi Yamamoto

Director of the Medical Information System Development Center/Visiting Professor of Jichi Medical University; graduated from Osaka Medical College; physician and doctor of medical science; specialized in safety management of medical information and privacy protection in medical care. His published research includes Protection of Personal Medical Information and Security (co-authored) (Yuhikaku Publishing), All About the Social Security and Tax Number System (Nikkei BP), and Utilization of Medical Information and Protection of Personal Information (EDITEX).

Medical Care and Privacy: The Importance of the Rights of Patients

Medical care is based on the study of medicine, and the advancement of medicine requires access to human data. At the same time, **personal information such as medical history and physical condition is concerned with the privacy of individuals**. These data are important for medical treatment, but they can disadvantage certain individuals in certain cases. For example, someone who has been operated for cancer may be refused an important role at work due to the risk of the recurrence of the disease. Some people are also concerned that hereditary diseases may disadvantage them in marriage and employment. Such discrimination caused by judgment based on prejudices and preconceptions is a serious problem and should not be tolerated.

Since extremely sensitive personal data is handled in medical practice, **doctors and pharmacists are required to comply with the nation's criminal laws and serious penalties are imposed for violations in the protection of confidentiality**. Nurses and public health

professionals are also required to maintain confidentiality, as stipulated in the laws related to their medical qualifications. At the same time, the Personal Information Protection Act contains provisions to protect individual information in general. [This law also stipulates that medical data should be handled with particular care.](#)

Although law requires confidentiality of information, only a few doctors have ever been accused of violations. Since the confidentiality of information is considered an ethical obligation of professionals engaged in medical practice rather than a legal obligation, it is very well protected in Japan. [The World Medical Association announced the Helsinki Declaration and the Lisbon Declaration for doctors from most parts of the world.](#) These declarations emphasize the importance of using patient data with great caution. These documents represent sets of non-legally binding ethical principles that define the rights and obligations of patients to receive medical services, including [the right to information on their disease](#) and [the entitlement of protecting it from others.](#) These principles are also observed in Japanese medical practice.

The protection of privacy and personal information

We all have information about ourselves that we want to keep private. The right to privacy is **the right to protect** such secret information and it is recognized as a human right guaranteed by the constitution. It is considered **an individual's privilege to control personal information** to prevent private and secret information pertaining to a particular person from being disclosed or used for purposes other than those for which it was initially intended without the permission of the concerned person. Let us use the following example of online shopping to explain this rather complex concept of protection of privacy and personal information.

You want to buy hot sauce online and need to provide the seller with some of **your personal information such as your name and address**. You will assume that your name and address will be used to send you the ordered item. Since you agree with the purpose of use of your personal information, your privacy will not be violated if the

seller collects, stores, and uses your name and address.

However, what if the hot sauce seller gives your name and address to another company and that company sends you an e-mail advertising red chili paste? Since you like spicy food, you may be tempted to buy the product, but you will not like the fact that some company you do not even know has your personal information. **This instance represents a case of the violation of your privacy as your personal information was used for purposes other than those for which you had agreed.**

In the event that a business operator handling personal information uses such information for improper purposes or discloses it to a third party without the consent of the information provider, the business operator will be obligated to suspend its operations or delete the information. This obligation is prescribed by **the Personal Information Protection Act**, which is explained in the section that follows.



Personal Information Protection Act

In Japan, the Personal Information Protection Act came into force in 2005. The Act was significantly revised in 2017. The Personal Information Protection Act is closely related to privacy, but it is a law designed to prescribe the duties of companies that handle personal information rather than to protect the right of the information provider.

Since privacy is a right, the interest of every individual should be considered supreme. However, the degree of importance of personal information varies according to the type and the holder of the information. For example, while storeowners will have no problem sharing their store address with anyone, celebrities will try to prevent the public from knowing where they live. It is difficult to regulate individual circumstances by law; hence, the duties prescribed for business operators who handle personal information serve as the framework of the Personal Information Protection Act. The Act requires holders of personal information to

protect the privacy of those who provide their personal information.

However, the reinforcement of the protection of privacy makes it harder to use personal information even for appropriate purposes. Conversely, an overemphasis on convenience and a neglect of security can lead to problems such as information leakage. **Companies should develop and follow policies to maintain a balance between convenience and security.**

Points of the revised Personal Information Protection Act

The following two points are pivotal factors for the field of medicine:

◆ **Information related to the medical history of patients is now categorized as information requiring special handling**

☞ Personal information requiring special handling must be handled with extraordinary care and cannot be used unless the information provider gives firm approval.

◆ **The stipulation of anonymized information has been added**

☞ Anonymized information is personal information from which data such as name, address, date of birth, and gender have been removed to prevent the identification of a particular individual. Such information can be used without the information provider's consent.

Next Generation Medical Infrastructure Law

We hope that the explanations provided above have established the association between the accumulation of patient data and medical research, and that the importance of patient data to the advancement and development of medical technology is now clear. In addition to the privacy of individuals, [the concept of public interest](#) is important in the collection of medical data.

The public interest is “[the welfare of the general public.](#)” However, medical data do not bring immediate or direct benefits to all humanity. To be precise, the use of medical data is concerned with “[the future well-being of the general public.](#)” Between the seventeenth and nineteenth centuries, many people lost their lives because of diseases such as cholera, dysentery, and tuberculosis. At that time, there were no effective means to combat infections or diseases caused by bacteria. However, patients and healthcare professionals kept detailed records of their fights



against such diseases as well as the treatment and nursing care that was provided. The recorded data were examined later and were used for medical research, leading to the development of antibiotics that were effective against bacteria. The discovery of how people become infected has made it possible for us to develop resistance and to prevent certain diseases. Nowadays, few people die of cholera and dysentery. Some people may still suffer from tuberculosis, but the disease is curable with medication.

[Patient data from more than a century ago contributes to present public interest as they serve our needs today.](#) Although those data did not help the patients at the time they were recorded, diseases that are curable these days might have still been feared as intractable diseases if those data had not been used for scholarly research.

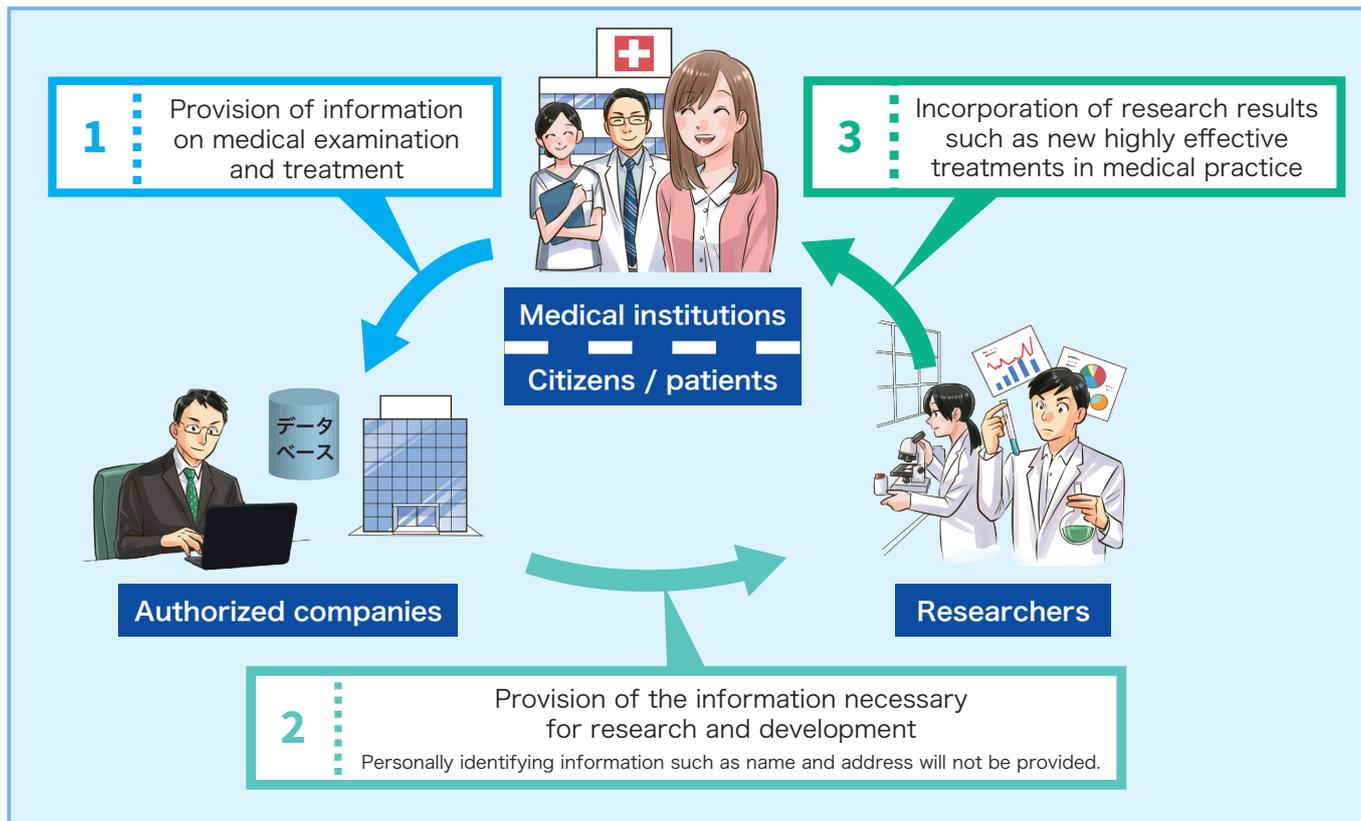
This above is an example of how medical data are used. The Personal Information Protection Act sometimes makes the use of data for public interest difficult. The Act is aimed at preventing the violation of privacy (e.g., identification and leakage of personal information) and thus emphasizes the importance of the



public interest. However, if it interferes with medical research, the development of new medical technologies, or the use of personal information to prevent a disease from spreading, the Act will ultimately render a disservice to the public.

Therefore, the Act Regarding Anonymized Medical Data to Contribute to Research and Development in the Medical Field, commonly referred as [the Next Generation Medical Infrastructure Law](#), has been established to promote more efficient and safer use of medical data through prior confirmation of the purpose of use for public interest and for the establishment of a system [to prevent the violation of privacy](#).

Companies require the authorization of the government to be able to obtain data from medical institutions. These entities are strictly examined and they are mandated to demonstrate that they are capable of protecting the privacy of the patients and that the obtained information will be used exclusively for public interest purposes. Medical researchers receive data from authorized companies to conduct their investigations.



3 Prevention of leakage of medical information

Q How is my medical information provided to companies?

A When your medical information is collected from medical institutions under the Next Generation Medical Infrastructure Law, the information is **encrypted** so that it can be read only if decrypted before being passed to authorized companies. **A special key, which is under strict control, is required to decrypt the encrypted medical information.** It is impossible for a third party to decrypt medical information once it is encrypted.



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Q Is it impossible to identify individuals based on information such as the name of the disease and age provided to researchers?

A The collected medical data are anonymized before being employed for research by converting dates of birth and consultation duration into ages and numbers of days or by classifying diseases into groups to make it impossible for people to know to which patient the original medical information belongs. Researchers receive the data altered in such a manner that will not affect their investigations. Authorized companies ensure that the anonymized medical data do not personally identify individuals before they are passed to researchers.



Anonymization to Protect the Identity of Individuals

The most important aspect of protecting privacy is to make it impossible for someone **to know to whom a particular set of data belongs**. However, it is not easy to change medical and health data into non-personally identifying information.

For example, it is almost impossible to identify an individual based on the information that he or she visited a university hospital in Tokyo on January 25, 2019. However, with the information that the person visited a medical institution in Tokyo on January 25, February 19, March 13, April 18, April 24, and May 15, 2019, his or her colleagues or friends may be able to identify that person based on other information such as that he or she took leaves of absence on those days. In such an instance, the first day of visit is not specified and the dates from the second visit onward are replaced with the expressions such as 28 days, 34 days, and 56 days after the first visit to make it difficult to identify the individual.

Since actual medical data contain more information, sometimes a data subject can be identified when analyzed in detail. Nevertheless, **it is possible to make the identification of individuals almost impossible by altering different types of data.** This process is called **data anonymization.** The Personal Information Protection Commission, a Japanese government commission charged with the protection of personal information, has made guidelines on the methods of data anonymization available to the public.

The personal data handled in medicine are highly sensitive compared with the information handled in other fields. For this reason, the Next Generation Medical Infrastructure Law sets forth stricter standards than the guidelines on data anonymization published by the Personal Information Protection Commission. It also requires the developed processing technologies to be considered in the use of data after anonymization. The use of data created based on such standards **prevents problems such as the identification of individuals based on personal information and stops the misuse of data.**

Encryption to Ensure Security

The medical data handled under the Next Generation Medical Infrastructure Law include all information about the medical condition of each individual patient. If third parties other than medical institutions or authorized companies gain access to this type of health data, there is a risk that the personal information and health conditions of patients may be leaked to third parties. This Law prescribes **the encryption of medical data before it is passed to authorized companies**. Encryption is the process of encoding information in such a manner that only companies authorized to receive the medical data can access it. Keys are used to encrypt medical information before it is collected and to decrypt it after it is passed to authorized companies. These keys are much longer than passwords we normally use. These keys are **strictly controlled** and they incorporate a system preventing encrypted medical data from being decrypted by third parties other than authorized companies and involved medical institutions.



Review points. "Secure Utilization of Medical Data"

✓ The utilization of medical data is crucial for the development of medical science.

- The utilization of patient medical (medical care) data is essential for the advancement of medical care, such as the development of innovative therapeutic drugs that can cure cancer, and the research of next-generation medical care such as IPS cells.

✓ Medical information is transferred under encryption so that the contents can not be easily disclosed to any third party.

- Incidents of leaks of confidential information including Internet crime and loss of USB memory have occurred frequently. It is considered important to protect the privacy of information handled by medical treatment.
- Medical data is encrypted using strictly managed proprietary information (electronic keys).
- Communication between healthcare providers and certified company is as secure against leaks and tampering as with online banking where money is exchanged over the Internet.

✓ Medical data is utilized after anonymization processing so that individuals can not be identified.

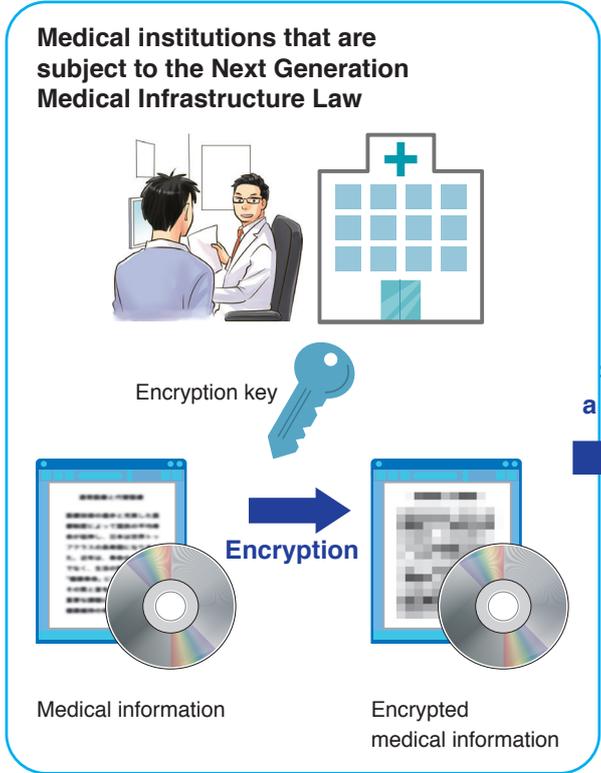
- Anonymization is a process of processing information partially to make personal identification impossible (such as generalizing and replacing with another character).
- Anyone can identify a person by anonymized information (cannot re-identify).
- Anonymization of medical information is performed on a more strict basis than general uses such as handling purchasing history (such as point cards) and transportation usage history (such as IC card tickets).



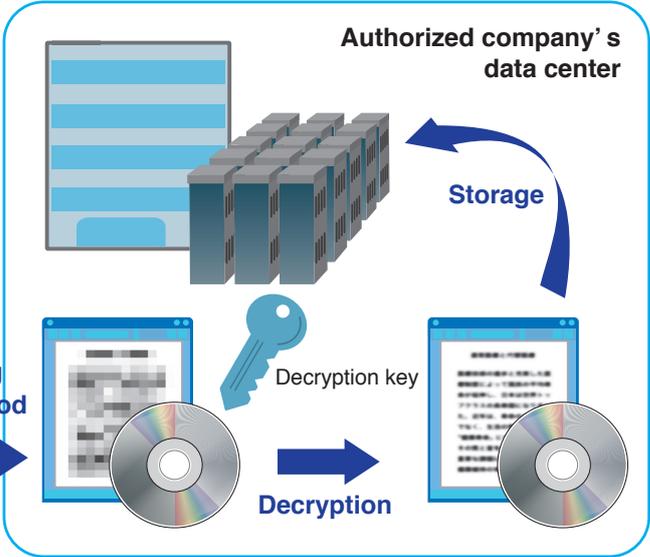
Data Exchange with Appropriate Measures

Encrypted medical data are sent to authorized companies either through a network line or through the use of a hard disk. **The same method as online banking is employed** for data to be sent through a network, and medical data cannot be deciphered while it is being collected. It is possible to track the delivery status when data are sent using a hard disk as a record of the delivery needs to be kept.

Medical data sent through a communication line are temporarily stored on a computer accessible from the Internet. However, once an authorized company receives them, they are transferred to a storage area strictly controlled by the company and **deleted from the computer** to which the data have been sent. This method helps **to prevent the diffusion of important information to unauthorized third parties**.



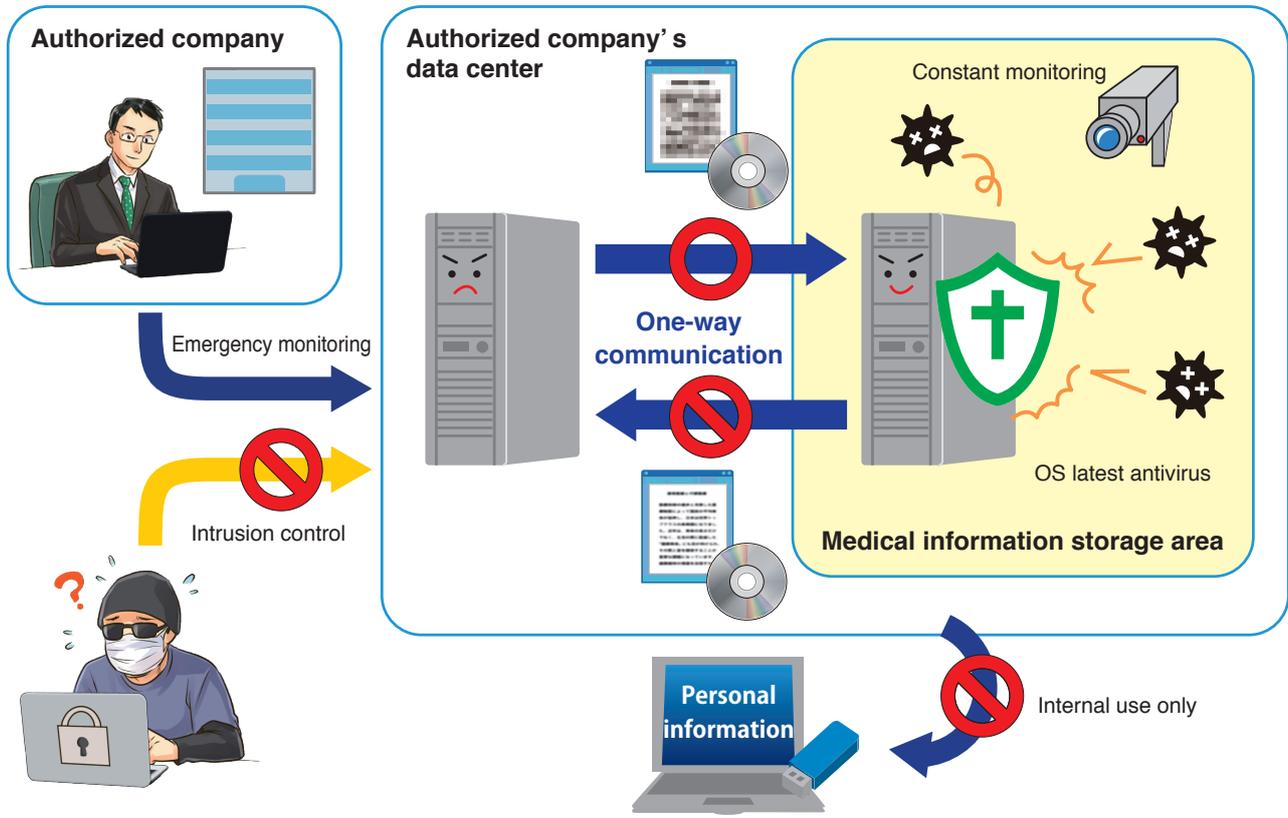
Sent using a safe method



Protection through Strict Security Surveillance

Medical data collected by authorized companies are anonymized and evaluated after being decrypted on computers managed by those companies. **All computers are kept up-to-date and are required to have antivirus software installed on their systems.** Computers storing collected medical data over a prolonged duration are programmed **not to allow any external communication** to prevent the unintended diffusion of medical data due to infection by computer viruses.

Computers managing medical data are located in a strictly controlled environment **to prevent the unauthorized access to and external use of the data.** At the same time, **all operations on computers handling medical data have to be recorded** by law.



4 For future medical care of our citizens



I understand that our medical data are important for future medical care. Do they serve other purposes than the advancement of medical technology?

A Japan is one of the few countries in the world that mandate a universal healthcare system. All citizens have health insurance and access to low-cost advanced medical care. In recent years, medicine has made remarkable progress in Japan. The country's mature medical system has facilitated the collection of patient data and has promoted the advancement of medical research. In doing so, it has contributed to the establishment of the current healthcare services.

You may not normally think too much about the universal healthcare system. However, medical care is [closely related to our lives in terms of the social security system as well as the technology used to cure diseases.](#)

Since the promotion of the use of medical data indirectly affects healthcare system reforms and the medical policies, medical expenses and insurance premiums are expected to decrease because of the streamlining of medical and nursing care services. It may take some time, but **providing more reliable and better quality medical and nursing care offers immense benefits to our society.**

Two important matters must be ensured to maintain the universal healthcare system. First, medical data should not be kept locked in storage; **instead, some aspects that are useful for research and development must be deployed for future medical purposes.** Second, **the privacy of the medical data of individual citizens should be protected by all means.** A person has the right to inspect personal information at any time and is entitled to refuse to provide personal data for research if there are any concerns. The data will continue to be used for the individual's treatment.

Japan has suffered significant damage caused by a number of natural disasters in the recent past. However, volunteers have helped and empowered many victims. **Your understanding and cooperation as a volunteer providing medical information will contribute to the future medical care of our citizens.**



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Pursuing both availability and security

We hope that by now you appreciate the importance of the analysis of patient data for the improvement of medical care and for the sustenance of the universal healthcare system. At the same time, patient data are sensitive personal information and their privacy should never be violated. Moreover, we have explained that the development of the Personal Information Protection Act has made it somewhat difficult for bona fide medical researchers to use patient data for the purposes of the progress of future healthcare.

We are sure that some of you would like to help those in need, volunteer to help victims of catastrophes such as earthquakes and floods, or make donations.

However, you should not invite trouble for volunteering or making donations. Likewise, using the data provided by patients should never violate their privacy.

A proverb states: “if you run after two hares, you will catch neither.” This



maxim implies that one cannot simultaneously do two things successfully and teaches the importance of focusing on one thing at a time. However, this axiom is not appropriate for patient data. According to the proverb, if we pursue both the effective use of patient data and the protection of privacy, we will achieve neither outcome. In fact, [there are ways to use data even as individual privacy is protected](#). One such way is the application of the Next Generation Medical Infrastructure Law. In team sports, we often hear the expression “[one for all, all for one](#).” This same is true of the future of our medical care. We must run after two hares.

Caring for the interest of every individual is the most important element of the protection of privacy. Although the Next Generation Medical Infrastructure Law stipulates all possible measures to be taken to protect privacy, patients can refuse to extend their medical data at any time. This action will not affect the medical treatment provided to those who do not want their medical information to be used for research or other legitimate purposes.



When you go to a hospital or a clinic in the future, you may receive a manual on the Next Generation Medical Infrastructure Law. We usually only go to a hospital or a clinic for health reasons and at such times, we often do not feel capable of thinking about other extraneous concerns. However, **your data will not be used for at least a month after you are provided a full explanation** about the Next Generation Medical Infrastructure Law. You can also deny the provision of your data at any time in the future. We recommend that you will remember the contents of this book and that you will make a reasoned decision whenever you are ready.

“Medical care is a part of our lives, and it is an essential thing. To make the mind and body a healthy and comfortable society, each one is interested in their own health and thinking about tomorrow's medical care it is important to go.



I want to know
a little more...

Let me help you



Legal system and related ministries related to "Mechanism of providing medical information"

Act Regarding Anonymized Medical Data to Contribute to Research and Development in the Medical Field (Act No. 28 of 2017)

Since the legislation has a rather lengthy and complex name, it is commonly referred to as the Next Generation Medical Infrastructure Law. The basic policy was approved in a cabinet meeting on April 27, 2018, and the law was enforced on May 11 of the same year. For more information, please visit the website mentioned below:

"Enforcement of the Next Generation Medical Infrastructure Law" by the Cabinet Secretariat Health and Medical Strategy Office

http://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai_kiban/houritsu.html

(Confirmed in March 2019)

Act on the Protection of Personal Information (Act No. 57 of May 30, 2003)

The often-heard term "Personal Information Protection Act" refers to this piece of legislation. It was the first privacy law to be enacted in 2003 and was revised in 2015, and the so-called revised Personal Information Protection Act was enforced at the end of May 2017. This Act establishes the basic policies, cabinet orders, rules, and guidelines, which are classified according to the founder and the business category. Please visit the website below for more information:

"Personal Information Protection Commission: Personal Information Protection Act" by Personal Information Protection Commission

<https://www.ppc.go.jp/personalinfo/> (Confirmed in March 2019)

Medical Information System Development Center (MEDIS)

MEDIS was instituted in 1974. The center assists in the promotion of security, standardization, and introduction of new systems for the popularization of a medical information system that is focused on electronic health records. It intends to contribute to the formation of a national healthcare system that is adapted for the advancement of medicine, to the improvement of national welfare, and to the development of the information society.

We have produced a comic version brochure “How to provide medical information? — A system of medical information utilization for tomorrow medical care”, in which we gently explain how to utilize your medical information. You can download it from the following website. Please read it!



Fair and safe use of Anonymized STandardized Health Data of Japan : FAST-HDJ<https://www.fast-hdj.org/>

※ An organization established by MEDIS-DC. We are promoting the utilization of anonymized medical information collected, that is useful for the progress of medical care and medical science.

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