

# International Conference on Current Situation and Challenges of Health Database in Each Country

-Security, Protection of Personal Data and Utilizing of Data-

## REPORT

1pm-5pm, May 13th, 2017  
JMA Auditorium, Tokyo, Japan



Japan Medical Association

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President-Elect, World Medical Association

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## Message

**Yoshitake Yokokura**

President, Japan Medical Association  
President-Elect, World Medical Association



The World Medical Association (WMA) adopted the Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks during the General Assembly held in Taipei last October. It was the revision of the Declaration of Helsinki (DoH) that prompted the WMA to address this issue. Adopted in 1964, the DoH is a set of ethical principles for medical research involving human subjects, including identifiable material and data of human origin, and it is one of the most highly regarded declarations of the WMA along with the Declaration of Geneva on medical ethics.

As the establishment of large databases increased, the WMA addressed the issues of health databases and biobanks during the 2013 revision of the DoH, and the Japan Medical Association (JMA) took part in the working group, joining in a series of discussions. The aim of the working group was to develop a document consistent with the DoH, that can be accepted by, and will widely influence, the world.

The super-aged society will soon arrive in Japan, and the government, with the collaboration of the JMA and prefectural medical associations, has established a national database on healthcare to help deliver proper healthcare. The JMA also announced new IT guidelines called the “JMA 2016 Declaration of IT Development” proposing to extend healthy life expectancy by centralizing the management of health check-up services using ID numbers. We are making efforts to support national health by maintaining the universal health insurance program and improving national health standards from the aspect of digital health.

Meanwhile, developments in the area of innovative technology can lead to securing medical care and preventive medicine and extending healthy life in an aged society, and it can eventually contribute to the establishment of a sound healthcare delivery system. However, as we face challenges, now is perhaps the most important time to re-evaluate where we stand from the viewpoint of medical ethics. The environment surrounding healthcare has many issues, and it is time that healthcare professionals, including physicians, seriously discuss the ethics, responsibility, and ideal approach to patients and consider how we can overcome various newly emerging problems. Based on such ideas, the purpose of the conference today is to provide a platform for discussions and examine the current status of health databases and their accompanying challenges in different countries, by inviting experts from the US, Korea, Taiwan, and Japan.

The WMA always closely watches the impact of its policy documents brought to each national medical association. As the President-Elect of the WMA, I wish to ensure that the WMA’s policy documents function as a driving force to broadly lead healthcare in the world in the right direction, and I am hopeful that I can bring a fruitful report to the WMA to contribute to future discussions.

## Keynote Address

# Current Situation regarding Health Database Utilization and Related Legislative Systems in Japan

Ryuichi Yamamoto

Chief Director, Medical Information System Development Center  
Invited Professor, Jichi Medical University



I believe that my task is to first explain the situation in Japan. So, I will begin with a brief review of the history on health databases in Japan, describe the progress of information and communication technology (ICT) in healthcare, and introduce health databases in Japan including some for biobanks.

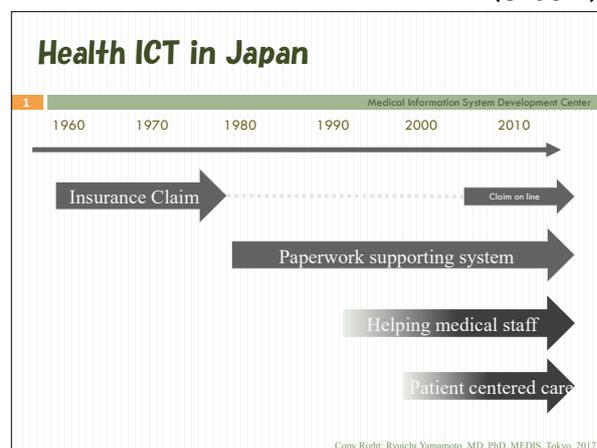
## Brief History of Healthcare ICT Development in JAPAN

The development of healthcare ICT in Japan was in fact quite advanced in the world until around the year 2000 (Slide 1). With the introduction of insurance claim processing software which began in the 1960s, the use of ICT relatively quickly became popular among healthcare institutions within the following decades.

As you all know, the government's universal healthcare program, when it first started, was mostly based on the fee-for-service system—namely, the reimbursement was based on the sum of all services provided, so a healthcare institution had to endlessly repeat an extremely large number of simple calculations to produce medical fee billing statements. This posed a considerable burden on the institutions.

Computers in the 1960s were quite incompetent—they were no match for the smartphones that everyone now has or even calculators of decent quality. Still, the task of repeating simple calculations over and over is easy for computers but extremely difficult and tiresome for humans, mean-

(Slide 1)



ing that the introduction of computers must have considerably reduced the amount of labor imposed on healthcare institutions. Because saving labor directly produces profit, ICT in healthcare rapidly progressed in this area in those years.

In the 1980s, soaring national healthcare expenditures arose as a problem, and the optimization of the healthcare costs without sacrificing the quality of care became a social challenge. This facilitated the streamlining of certain tasks, mainly in the area of administrative works that do not directly involve the delivery of care and the carrying of hard-copy papers between places. Furthermore, large hospitals started to adopt a paperwork streamlining system—the so-called “order entry system” or Ordering System (R)—in the 1980s. So, an economic motive was behind this change, and the certain degree of success had prompted larger hospitals to adopt such systems quickly.

The paperwork streamlining system was char-

(Slide 2)

Brief History of Healthcare ICT in JAPAN	
2	Medical Information System Development Center
1970s	Computerized financial systems
1980s	Order Entry systems of large scale hospitals
1999	Government determined requirements for paperless EMR.
2001	"Grand Design for Healthcare ICT in Japan"
2005	Enforcement Personal Information Personal Act
2006	"New IT Reform Strategy"
2010	"A New Strategy in ICT"
2014	"Japan revival strategy"
2017	Enforcement of Amended Personal Information Protection Act
2017	Act for Authorized Provider of Deidentified Health Data (Health Infrastructure for Next Generation Act )

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acterized by data entry at the point-of-origin, namely, entry is made to a computer system where the information was created. This meant that computers were brought onto the scene of medical practice. Having computers available at the sites of medical practice not only streamlined the administrative processing but also led to the development of the electric medical records (EMR) system, which was intended to assist healthcare workers and patient-oriented medical practice.

However, the EMR system offers less incentive compared to the previous two ICT developments. For this reason, the EMR system has been introduced at the healthcare institutions—and has had real benefits—rather gradually instead of rapidly spreading. Nonetheless, most large hospitals have already adopted an EMR system, and most newly opened clinics are also using this system. So, I believe it will continue to spread gradually.

Along with these developments, the government has taken various measures (Slide 2). In 1999, when the EMR system was still in the experimental development stage, the Ministry of Health, Labour and Welfare (MHLW) made an announcement that healthcare institutions could operate the EMR system without producing any printouts at all. The government has continuously promoted ICT introduction by creating the “Grand Design for Healthcare ICT in Japan” as well as implementing various policies, but there has been a change in its direction since 2005.

The main theme until 2005 was how computers could be introduced into healthcare institutions,

(Slide 3)

Action Plan 2006 (Health field)	
3	Medical Information System Development Center
Make New Grand Design for Healthcare ITC	MHLW announced first draft and emphasizing constructing Japanese EHR
Common Infrastructure	Healthcare PKI ,Secure Network, and Healthcare smart card
ITC Based Healthcare Network	Regional and inter-regional healthcare network
Gathering nation-wide health data and analysis.	Developing healthcare terminology and ontology
Full Online Handling of Insurance Claims	

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but since 2005, it has been changing to how electronic/IT information can be utilized better.

The first movement was the Personal Information Protection Act (PIPA), enacted in 2005, and the New IT Reform Strategy, released in 2006. A new strategy in ICT was announced in 2010, and the Amended PIPA, the original version of which was said to be somewhat insufficient, was enacted on May 30 of this year. At the same time, a new law aiming to promote the positive use of health data passed the National Diet during the last days of this past April.

The 2006 New IT Reform Strategy listed the structural reform of healthcare by making IT the first priority. To be more specific, the intended plans included creating a grand design; preparing a common platform; developing healthcare public key infrastructure (Healthcare-PKI or HPKI) for the license authentication of physicians; building a secured network for healthcare use, which the JMA is currently working on as a main facilitator; and developing a Healthcare Smartcard for patients that differ from the personal ID card (“My Number Card”) issued by the government (Slide 3). As for the health database issue, a proposed goal was to promote evidence-based healthcare policy development and evidence-based practice of medicine by collecting data across the nation and through securing people’s privacy.

However, the i-Japan 2015, which was formulated in 2010, lived for only a very short time because the ruling party of the government changed only a month after it was announced, after which

(Slide 4)

**Data Oriented Projects in Japan**

4 Medical Information System Development Center

- National Insurance Claim and Health Check-up DB (NDB)
- Mid-Net Project (PMDA & MHLW)
- KDB
- Nursing care evaluation DB
- Nursing care insurance claim DB
- National Cancer Registration
- National Clinical DB
- .....
- Medical Genome Center Biobank (National Center for G & G)
- Tohoku Medical Megabank Organization

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(Slide 6)

**Insurance Claim data**

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- Date of birth (only month and year values)
- Diagnosis
- Data of beginning of care and number of days for care
- Health institute ID
- Kind of visit
- Existence of educational guidance
- Prescriptions with drug code, Injections with drug code
- Codes of medical procedures, Codes of Surgical Operations
- Codes of laboratory, physiological and radiological examination (without results)
- Codes of Imaging diagnosis
- Total costs
- Double hashed value of Insurance claim ID, birth date and gender
- Double hashed value of Name, birth date and gender

**Health check-up data for life style related diseases**

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- Date of check-up or educational guidance
- Code of Health plan
- Code of examination institute
- Gender and postal code
- Results of examinations and educational guidance
- Level of educational guidance
- Double hashed value of Insurance claim ID, birth date and gender
- Double hashed value of Name, birth date and gender

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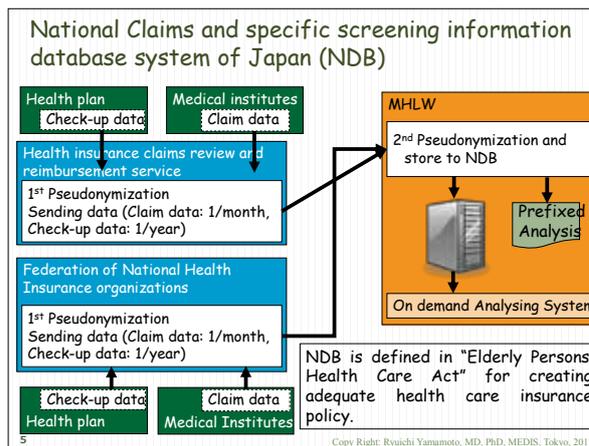
the i-Japan 2015 died out. Nevertheless, the full utilization of anonymized data was one of its targets.

## Health Databases in Japan

After these events, the development of health databases in Japan finally began at around 2005 (Slide 4). The National Database of Health Insurance Claims and Health Checkups of Japan (NDB) is a database of the MHLW that contains all insurance claims (called “receipts”) and all cases of specific health check-ups. The MID-NET is a database created for drug safety. Furthermore, a database containing all EMR data, including lab test results—not insurance claim data—from 10 hospital groups of 23 hospitals in total across the country has been created and is now operational. Many other databases have also been created.

These two at the bottom of slide 4 are biobanks, not health databases. The National Center for Geriatrics and Gerontology has been operating its

(Slide 5)



biobank, called the Medical Genome Center (MGC) Biobank, for over 10 years now, but comparatively few specimens have been collected yet. The Tohoku Medical Megabank was created with the intention of making the Tohoku Region a top healthcare developed area after the Great East Japan Earthquake.

Slide 5 shows how the insurance claim data and specific health check-up and guidance data are collected by the NDB, the first and largest health database in Japan. The process of pseudonymization is repeated twice to ensure irreversible anonymization. The MHLW’s database is shown on the right. The same process for anonymization applies to the specific health check-up and guidance data. This database was constructed in response to the Act on Assurance of Medical Care for Elderly People.

Contained in this database are the data shown in Slide 6. All identifiable information within the insurance claim data, such as the policy type code, policy number, date of birth, gender, and name, is blocked out by replacing them with hash marks, while the other data remain in the database. One thing that stands out here is that the ID numbers of healthcare institutions remain intact. The same is true for the specific health check-up and guidance data: the identifiable information for these individuals is carefully hashed and removed, while the ID number of the individuals and institutions that performed their health check-ups remain.

In terms of anonymization, generally identifiable data are so carefully removed that it is impos-

sible to identify a person using the normal data, for both the insurance claim data and the specific health check-up data. However, the ID numbers of the healthcare institutions that submitted insurance claims or health check-up data remain. In that sense, it is technically possible to perform an analysis on a particular clinic, for example a clinic run by a private practitioner, without compromising patient privacy. The possibility of identifying exact individuals is thus still not zero when the care provided was extremely rare or when extremely rare drugs were used, even without their names or dates of birth.

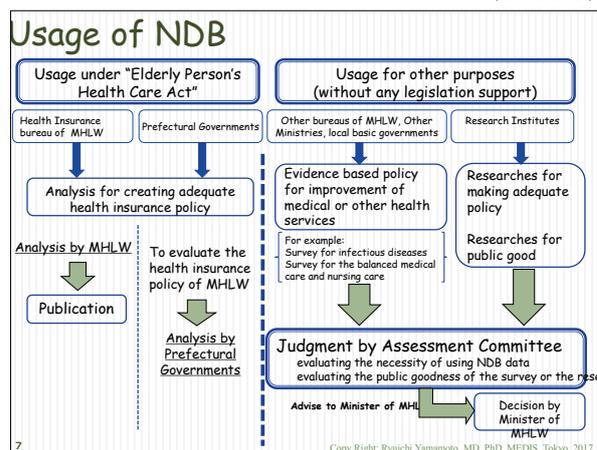
It is also possible to link data that belong to the same person because the hashed value will be the same. Thus, it is technically possible for someone familiar with a certain patient to identify the source of the information from medical history or health check-up record data over a very extensive period. For this reason, the NDB data are regarded as normally un-identifiable, but not fully anonymized.

As for the volume of data accumulated, there are approximately 12 billion pieces of insurance claim data and 200 million pieces of health check-up data. All of them exist as individual data, and there are also sample datasets available besides these individual data. A sample dataset can be created by sampling the 1% of outpatient data and 10% of inpatient data of a given month, and replacing unique data such as that for very rare diseases, medical procedures, and drugs with dummy data.

The other type of sample datasets is called a basic dataset. This dataset also contains 5% of the data of a given month, and is available such that the data from the same patients can be linked together. It has been debated recently that this dataset might be more useful with some additional information, such as the zip codes to indicate the areas of residences.

So far, about 140 research projects have received sets of individual data, sample datasets, and basic datasets. From these projects, over 100 peer-reviewed scientific articles have been published already—all from the NDB database.

(Slide 7)



As for the procedure regarding data delivery, this database was created according to a law, as I mentioned earlier. Therefore, the pieces of data that are regulated under the law must follow the provisions of the law. However, other pieces of data not stipulated in the law are available for study because this database is intended to strongly serve the public interest. Various researchers and organizations affiliated with municipal governments and the national government are currently making use of the NDB in the interests of public good and safety (Slide 7).

The availability of data for such use is not stipulated in the law, so guidelines had to be developed first. Applications for use of these data are accepted if they meet the bare minimum prerequisites of securing the public benefit and ensuring non-disruption of the patients as well as the healthcare institutions, checkup facilities and insurers that submitted insurance claims for medical fees and specific health check-ups and guidance.

The Board of Experts, which consists of experts and representatives from the JMA, the Japan Dental Association, and the Japan Pharmaceutical Association, in which I serve as a chairperson, examines each application submitted, ensures that “this project will contribute to society” and that “it will not cause trouble for the patients and healthcare institutions.” We then advise the Minister of Health, Labour and Welfare to provide the requested data. Upon receiving our advice, the Minister of Health, Labour and Welfare then provides the dataset. This system of data delivery has been

## Japanese Sentinel Project (Mid-net project)

Medical Information System Development Center

- Based on distributed database model, with common data set and standardized query process model.
- Common data model consists of SS-MIX and other international standards.

SS-MIX:  
Standardized Structured Medical record Information eXchange  
Based on HL7 version 2.5 messages, CDA R2, and DICOM  
Over 800 hospitals already implemented SS-MIX standardized Storage system.

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operational for about 8 years now.

Now, I would like to explain another health database, the MID-NET (**Slide 8**). This database was created under the Japanese Sentinel Project, which was inspired by the Sentinel Project proposed by the US-FDA. Unlike other commonly created health databases, this is a distributed database—namely, data are physically located at individual health institutions after being converted into common data models.

In this project, the hospital databases based on a common data model are given a standardized query (search/extract) language and somewhat standardized statistical processing language, and the databases then return their results. Therefore, the data never really leave the hospitals.

The SS-MIX2 standard, which is a MHLW standard, is used as the common data model. Its contents are a combination of globally accepted basic standards such as HL7 and DICOM, and a Standardized Storage System is housed in each hospital so that all hospitals can receive a shared inquiry and each hospital can answer it.

For example, the accumulated data can amount to 10 million persons in 5 years, so even a drug that only one in every 100,000 people uses will be used by roughly 100 persons. In this project, which became operational this year, data collected from different hospitals are used to study the adverse effects of different drugs or to examine the effect of countermeasures against certain side effects.

For example, in an EMR database of the MID-NET Project, a standardized storage is created in

National Center for Geriatrics and Gerontology      Medical Genome Center Biobank



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each hospital. After the data extraction system and the removal of the ID information, the data undergo statistical processing and extraction to provide answers in the common language. The resulting files produced at multiple healthcare institutions from this process are then integrated and analyzed, to possibly reveal rare adverse effects or enable early detection. This project is operated mainly by the Pharmaceuticals and Medical Devices Agency (PMDA), which is equivalent to the US-FDA.

However, one drawback to the MID-NET is that only the data from major hospitals are available. Therefore, this project might not function well for a disease for which patients do not commonly seek care at major hospitals or a drug that is not commonly used at major hospitals. There is a vision to gather data from nearby clinics at each major hospital, but nothing about this has yet been done.

Although they are all major hospitals at present, 23 hospitals across the country are participating in this MID-NET project, including NTT Group hospitals; university hospitals at Tohoku University, the University of Tokyo, Chiba University, Hamamatsu University, Kitasato University, and Saga University; and Tokushukai Group hospitals.

### Biobanks in Japan

As a very brief introduction of a Japanese biobank, I would like to mention the Medical Genome Center Biobank, which the National Center for Geriatrics and Gerontology in Osaka has been operating for over 10 years (**Slide 9**). Its scope of operation is not very extensive, so the number of

(Slide 10)



specimens is not too great—still, it is a biobank that has been available for a long time.

Slide 10 shows the homepage of the Tohoku Medical Megabank. As for how much progress it has made, they are in the process of building what they call “local community cohorts,” in which as many individuals as possible within each community, mainly along the coastline, are asked to participate. Reportedly, the Megabank has already obtained consent from about 80,000 people.

Another cohort they are working on is the 3-generation cohort, which is a tracking survey of three generations. Consent is often obtained at the time of childbirth, and so far, 70,000 people have given their consent. Some participants overlap between these studies, so the total number of participants amounts to about 140,000. As for the outcome, which is still at this point very limited, they are trying to create a whole genome reference panel for the Japanese people. The whole genome analysis of 2,049 people has been completed thus far.

In following the exact same methodology and being conducted at the exact same lab by the exact same people, this is an extremely high-quality reference panel. In the past, the data of only 80 people or so were available, but now 2,049 people’s data have been added to the reference panel of the Tohoku Medical Megabank. Investigations of these data have already revealed 27,997,593 single nucleotide polymorphism (SNP) variations, or single gene mutations, in total. Of these, 9,671,410 were already known, which means that 18,326,183, or 65.46%, were newly found single gene muta-

tions. So, this project has already succeeded in identifying new SNP variations

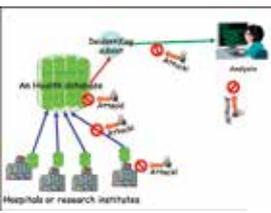
## Rules of Operation and Security

The operation of biobanks and health databases is debated by the stakeholders each time a new biobank or database is planned, and they also discuss how to ensure the trust of the public or patients. However, the need to standardize the rules has been voiced for a long time.

The protection of privacy is a priority; this can never be infringed. Having informed consent is optimal for privacy when possible, but it is not always possible to identify all possible purposes of use when collecting data for a health database. Rather, points that should be investigated often later develop, and it is impossible to know ahead of time if a patient will develop an adverse effect for a drug, although that should be investigated thoroughly when it occurs. So, health databases and biobanks are an area where it is extremely difficult to obtain solid informed consent because all purposes of use cannot be identified at the time of consent.

Even without solid informed consent, there are several methods that can ensure the protection of patient rights or that will not put an unfair disadvantage on a specific healthcare institution. One is having a well-maintained legal system as well as ethical codes that are widely accepted by people in many different sectors, including the research community, data users, and data providers. The WMA Taipei Declaration that President Yokokura described earlier is definitely a candidate.

Combining these methods will likely ensure the correct and fair use of these data among data users and data providers; however, another important thing is information security. When data are stolen, no one can control what will happen afterwards. The law and ethical codes are sufficient when things are under control, but they are quite useless when such control is lost—so it is important to make sure the data do not get stolen. Therefore, information security will play a very important role.



"Database" includes:

- > gathering data from various institutes
- > indexing or preprocessing native data
- > send subset to various analysts
- > .....

There are so many attack points!

Deep Freezer is so heavy and easily locked. It seems to be more secure than information database

But... Biobank is further worthwhile with health database!

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A health database will not function if it simply consists of a computer with data discs and a database inside (Slide 11). First, data must be collected. Second, the collected data must be used. Risks exist in each process. Now, there are some points to attack. These attack points have to be clearly identified and managed. This is quite a tough task, and I believe that security is truly an eternal challenge. Just recently, the NHS of the UK was reportedly hacked, and it seems there is no end no matter how much you try. Still, we have to continue working on it. In short, this is an area for the risk has to be reduced to an acceptable level.

As for biobanks, their collections are biological specimens, so they are generally stored in deep freezers. A deep freezer is extremely heavy and has quite a strong door, and it is not difficult to block the access. Basically, it is relatively not difficult to prevent the stealing of specimens from a deep freezer—it is far easier than is ensuring information security. However, biobanks alone are not much useful. A biobank with tissues and cells to extract genes, for example, is not very useful without the information on what kind of patient the cells are obtained from.

Therefore, a biobank is naturally accompanied by a health database of this sort. A biobank and a health database together, with additional information such as clinical findings, can be significantly meaningful. The outcome of the Tohoku Medical Megabank so far was the result of a sample analysis; it did not require clinical findings. In the next step of the study, the types of SNP variance that

### Personal Information Protection Act (PIPA), 2005

12 Medical Information System Development Center

- Chapter 1. General Provisions (Articles 1 to 3)
- Chapter 2. Responsibilities of the State and Local Public Bodies, etc. (Articles 4 to 6)
- Chapter 3. Measures for the Protection of Personal Information, etc. (Articles 7 to 14)
- Chapter 4. Duties of Entities Handling Personal Information, etc. (Articles 15 to 49)
- Chapter 5. Miscellaneous Provisions (Articles 50 to 55)
- Chapter 6. Penal Provisions (Articles 56 to 59)
- Supplementary Provisions

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exist for diabetic patients, for example, should be investigated—in fact, such a study is already underway. Naturally, a similar study should be carried out on other diseases, but a database has to be considerably large to study a rare disease.

Therefore, privacy protection as well as information protection are very important for the safe operation of biobanks, too. Collecting clinical information when these security aspects are insufficient poses an extremely high risk. A biobank contains materials that allow one to analyze all known genes if one wants, and a health database contains all clinical information; exploitation of both as a set can be extremely problematic. Therefore, I believe a database for a biobank should be under more strict management than a regular database.

## Japanese Legislative System on Privacy Protection

Next in Slide 12, I would like to briefly introduce the content of the Personal Information Protection Act of Japan (PIPA), which was completely renewed in 2005. This law, which laid the foundation for privacy protection legislation, is characterized by a major feature—that is, a different system was in place for each sector. Another way of saying this is that a different set of rules exists for administrative agencies, independent administrative corporations, and municipal governments. The rules themselves are not so different, but the primarily responsible person is different because these organizations belong to different systems.

(Slide 13)

Security Guidelines for Health Information Systems  
MHLW 2005 - 2017

Medical Information System Development Center

**13**

- 1. Introduction
- 2. How to Interpret the Guidelines
- 3. Scope
- 4. Responsibility for Handling Electronic Health Information
- 5. Interoperability and Standardizations
- 6. Basic Security Management of Health Information Systems
- 7. Requirements for full digital systems
- 8. Requirements for Outsourcing of Data Storage
- 9. Scanning or Digitizing of Analog Data.
- 10. Operation Managements
- Appendix 1. Sample of rules for Basic Security Measurements
- Appendix 2. Sample of rules for Full Digital Systems
- Appendix 3. Sample of rules for Outsourcing of Data Storage

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In the case of healthcare, there are hospitals run by municipal or prefectural governments, hospitals run by independent administrative corporations, and a few healthcare institutions run by the national government, while most other healthcare institutions, including long-term care institutions, are run privately. Therefore, the primarily responsible persons under the law would differ among these institutions. To be specific, the Minister of Health, Labour and Welfare is responsible for privately-owned healthcare institutions; the Minister of Internal Affairs and Communications is responsible for institutions run by the national government; a chairperson of an independent administrative corporation or the Minister of Internal Affairs and Communications is responsible for institutions run by an independent administrative corporation; and the head of a local autonomy, mayor, or governor is responsible for institutions run by a municipal/prefectural government.

This means that the input of many different people responsible for privacy protection needs to be collected before sharing health data among these institutions. Reportedly, this is one factor that is negatively influencing health data sharing in reality. This is a major shortcoming.

**Slide 13** shows the MHLW's security guidelines for information management, which are based on the above-mentioned PIPA. These guidelines are revised almost every year, and the 5th edition will be published soon. Security needs to change in accordance with the changing technology; it is not something that remains acceptable for 5 or 10

(Slide 14)

Security Guidelines for Health Information Systems  
MHLW 2005 - 2017

Medical Information System Development Center

**14**

Chapter 6: Basic Security Management of Health Information Systems

- 6.1 Policy and Disclosure
- 6.2 Identify the Data and Risk Analysis
- 6.3 Organizational Security
- 6.4 Physical and Environmental Security
- 6.5 Technical Security
- 6.6 Human Security
- 6.7 Discard of Health Data
- 6.8 System Development and Maintenance
- 6.9 Taking out Information and Information Equipment
- 6.10 Emergency Action in Disasters or Other Incidents
- 6.11 Security for Information Exchange with Networks
- 6.12 Electronic Signature

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years once a rule is established. Every new technology requires new guidelines to match, so the MHLW's guidelines are revised very often.

I want to draw your attention to Item 6 on basic security (**Slide 14**); these guidelines advise on developing a policy and making it available to the public and performing a risk analysis, and talks about security in terms of organizational, physical, technical, and human-resource perspectives and the destruction of health data. Healthcare delivery is continuous, but IT systems do not last as long. Every 5 or 6 years, hardware must be modified, and such maintenance issues are also dealt with in the rules.

There are other situations to consider, such as when a physician is making a house call or providing home care and information has to be taken outside, when a large-scale earthquake or disaster occurs, or when is system is under attack by a hacker. What needs to be done then? The guidelines provide all the above, describing how to exchange medical/health information via network, and introducing a guideline for electronic signature at the end.

The rules of operation of every health database, including the NDB and MID-NET, all refer to the MHLW guidelines, which must be adhered to. So, this part is more or less the standard point-of-reference in terms of the security of health databases in Japan at present. Naturally, any flaws, loopholes, or overlooked items are a serious problem, so every caution should be taken in the repeated revisions.

The revision of the PIPA has been in progress for 3 to 4 years now. First, the Act of 2005 provides rules, but they are very reserved and extremely loose when it comes to penalty. The unit of enforcement was an organization, and the rules were insufficient to control and deter those who have truly ill intentions.

Another issue was the usefulness of the Act. Personal information can help develop society as a whole through its positive use. The Act was established to set rules for not causing any inconvenience to individuals and to avoid violation of their rights; however, as the name of the law implies, the operation of the law tended to focus too much on “protection.”

Additionally, the Act did not define what constituted personal information—namely, it did not clearly lay down the standards as to how far identifiability had to be reduced for personal information to no longer be considered personal. Therefore, one person might think that erasing names and dates of birth from personal information is enough to use the information freely without consent on the one hand, while on the other hand, someone else might think that erasing names and dates of birth is not enough because the source can still be identifiable through street addresses or shopping history. Such extremes in opinions fed people’s anxiety.

Understandably, this anxiety made both the user side and the source side feel unsure. So, the law was revised to ensure how “this sort of information can be used” and “we will never inconvenience you because we have de-identified your information this much.”

I will now list some characteristics of the revised Act, which came into effect on May 30th. One that is relevant to both health databases and biobanks is the creation of Identifying Codes (i.e., personal identification codes). This is information that alone allows us to identify the exact individual. For example, a passport number is unique, so a passport number alone can allow one to identify the exact individual.

A genome sequence is also considered a type of

Identifying Code. A whole genome is naturally an identifiable code; however, it is yet not defined in detail as to how small the genome information should be to be no longer considered personal information. The Personal Information Protection Committee has issued a set of standards for the time being, but more deliberation is believed to be necessary.

Another thing to consider is the “weight” or sensitivity of the personal information—some information is heavy or highly confidential, whereas some is light or not so sensitive. For example, a point card is used when shopping at a grocery store. It creates data on who bought what at how much at a store, and this is considered personal information—the same applies to a medical record at a hospital. Prior to the revision of the Act, both shopping history data and medical record data were equally considered personal information.

In the revised Act that has adopted the concept of sensitive data, however, shopping data and medical record data are treated differently. Almost all health data are designated as sensitive data. Once classified as sensitive data—technically called “personal information with due consideration” in Japan—the data cannot be obtained without the consent of the source individuals. Sensitive data cannot be offered to a third party without consent, and the purposes of use cannot be changed. For other types of data, there is an option of “opting out”—that is, the intent to offer data to a third party is made widely known to the public, and the data can be made available upon notifying the Personal Information Protection Committee if rejection is not received from the individuals. However, this “opt out” is not allowed for sensitive data under the law.

With this revision, healthcare institutions in general such as hospitals, clinics, long-term care facilities, or health check-up centers cannot offer patient data to anyone without first obtaining the individual patient’s consent. In this sense, a genetic analysis for a commercial purpose might be performed with his/her consent, but the risk of his/her materials being used for other intentions has been

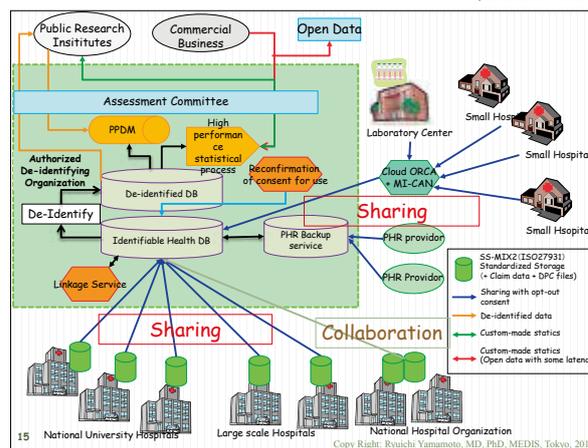
greatly reduced. In a way, the revised Act probably is a more reassuring piece of legislation for people.

On the other hand, medical and health information is not just used for individuals—in fact, medical knowledge contained in medical school textbooks are produced entirely based on patient data. In this sense, medical students and professionals utilize knowledge obtained from a considerable body of personal information to serve patients in return. If personal information can be used only for the recovery or maintenance of one’s own health, this also means that the information is not available for future medicine as well. This is one area in which the revised Act has created some concern.

### Positive Use of Health Data for Medical Research in the Public Interest

For this reason, the next-generation healthcare infrastructure law just passed the National Diet this past April (Slide 15). This law defines a service provider responsible for anonymization who will provide personal information exclusively for the purpose of medical research and technology innovation with the public interest in a way that it will never infringe the privacy of the individuals. This Authorized De-identifying Organization For Health Data is a service provider that meets certain criteria and is authorized by the government. Each healthcare institution is allowed to collect patient information on an opt-out basis for the Authorized De-identifying Organization’s use after carefully informing the patients. Having a notice on a bulletin board and waiting for the word “no”

(Slide 15)



is not good enough; a patient has to be instructed to read the notice on a bulletin board, and if the patient does not refuse, and only then can the information be collected.

An effort is currently underway under a law to establish a system to de-identify (anonymize) and provide these data upon fully reviewing the purposes of use based on appropriate standards, and ensuring that the purposes can be met and that the individuals and the institutions from which these data are obtained will not be inconvenienced, discriminated, or unjustly judged in any way. This law, commonly called the Health Infrastructure for Next Generation Act, is a brand new legislation, and its detailed operation is still waiting to be established. Nevertheless, this law marks the starting point of creating a legal system that promotes the proper use of health data including medical services and healthcare.

This concludes my presentation regarding the movements on health databases in Japan. Thank you for your attention.

## ○ Lecture 1 ○

# Improving Health with Databases and Biobanks: Promise and Pitfalls

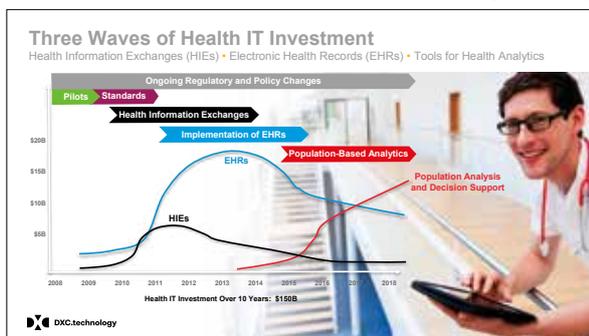
Robert Wah

Former President, American Medical Association

[@RobertWahMD](#)



(Slide 1)



(Slide 2)



**WHAT IS IT?**

**Precision medicine** is a groundbreaking approach to disease prevention and treatment based on people's individual differences in environment, genes and lifestyle.

The *All of Us* Research Program will lay the foundation for using this approach in **clinical practice**.

**WHAT ARE THE GOALS?**

Engage a group of **1 million or more U.S. research participants** who will share biological samples, genetic data and diet/lifestyle information, all linked to their electronic health records. This data will allow researchers to develop more precise treatments for **many diseases and conditions**.

I would like to speak today about health databases and biobanks and how we can use them to improve the healthcare of our patients. I believe that there is both promise and pitfalls in the use of health databases and biobanks.

## Three Waves of Health Information Technology in the United States

When I think about health information technology in the United States, there are really three waves on which that has happened (**Slide 1**). The first wave was that we moved from paper records to digital records, and we spent about 30 billion dollars making this happen.

Then we spent about another one billion U.S. dollars to make health information exchanges so that we can connect the digital information we now have. Once we have the network-connected digital information, we enter the third wave; a new phase of population analysis and decision support.

As a physician, this is the interesting part for me in all of this. I am not so interested in the technol-

ogy, the bits and bytes and boxes of getting digital information together. I am more interested in what we can do with the information once we have it in a digital format, and that is where I think we are right now. We can use very powerful technology and computers to analyze the digital information we have to help our patients become healthier and stay healthy.

## “All of Us” Research Program

I would like to turn to a project that we are just about to start this month in the United States. The name of the project is the “All of Us” Research Program. It comes out of our goal of providing “precision medicine” for our U.S. citizens. What we mean by “precision medicine” is that we want to tailor treatment specific to an individual (**Slide 2**).

In the old days when a patient came to my office and was diagnosed with diabetes, we would say for diabetics this is what we do for all diabetics. But now with personalized medicine, we can say

for you—a 32-year-old single mother, Hispanic left-handed female, with these four medications and these three aspects of your family history—for **you**: this is the right treatment for your diabetes. It is different from what we have done in the past when we provided blanket treatment to everybody. We can now personalize treatment, and use genetic information which enables even more personalization.

The “All of Us” Research Program in the United States is an effort to really accelerate the move towards personalized precision medicine. What it is, is we are going to collect blood and urine samples and health information from the electronic records of one million citizens across the United States. It will be a cross-section of old, young, female, and male patients across the entire United States. We are going to collect these biological samples, which could lead to the accumulation of genetic information on one million patients in one place, along with blood samples on which we can conduct many tests besides genetic analysis. The urine samples will also give us information about the metabolism of their biology, and then also we are going to have an ongoing stream of information from the electronic records going into our electronic database.

This will give us a very rich picture of one million citizens and will create a tremendous source of information for conducting incredible research and, we believe, making many exciting new discoveries. It is going to be a totally different way of conducting our research. In the old days we conducted clinical trials; we would say, “Okay, here are 200 patients with a particular disease; we are going to test a medication on them to see whether or not it is better or worse than the current medication.” By taking a million citizens, who each has a rich base of information, we will be able to use that database of information to do some really exciting studies and make discoveries about all kinds of diseases, not just one.

So, we will be able to not only treat but also prevent disease, and we are also going to look at the question of how we utilize technology to help

(Slide 3)



us engage with these one million citizens. We will be looking at mobile devices and other technologies to see how we can interact with these citizens.

Now, the way we are projecting this is, participation by voluntary citizens and they may not receive personal benefits from donating their blood and urine samples and medical information (**Slide 3**). That is why the project is called “All of Us”; it is because, by having all the United States citizens get involved in this study, we think that it will help all of the United States citizens, not just the individuals.

Ultimately we hope that this project will be very precise in giving the right drug for the right person at the right dose. It is due to kick off in May. The company that I work for, DXC Technology, is providing the citizen engagement technology. We are going to be working to engage the citizen through digital mechanisms as this new project rolls out, and we are very excited about the project.

### “Million Veterans” Program

Alongside this project, there is another project that is being conducted over about the same period of time called the “Million Veteran Program” (MVP) (**Slide 4**). In this project we are collecting the same samples—blood, urine, and digital information—but on one million veterans. These are men and women who have served their country in the military and have now completed their military service. So this is a different million patients from the “All of Us” population because they all served in the military. They were often exposed to some of the many environmental aspects of war-

(Slide 4)



fare, and the psychological aspects of warfare. This will be a different cohort to study, but it will still be a group of people to obtain rich information from, and will provide a source for future research and very exciting discoveries. The “Million Veteran Program” already has 550,000 volunteers signed up to participate, so it is a little bit ahead of the “All of Us” Program, which we are going to start in May of 2017.

These projects sound very similar to some of the research I have heard other countries are doing. Here in Japan we just heard about some database creation that has already started and will be on-going. I was in Sweden two and a half weeks ago, and in Scandinavia they have a long history of collecting information on their citizens. We are seeing this around the world, where governments and private agencies are collecting these new rich sources of information with which we will be able to do research and, I believe, make very exciting discoveries.

## Cyber Security

I want to talk about the security considerations that we need to keep in mind. I just showed you two projects in the United States that show great promise. Now, let’s talk about some of the risks and pitfalls that we have to think about as we gather this rich pool of information on our patients and citizens. I often say that I think health information technology for healthcare is really an intersection of health IT, cloud computing, and cyber security (Slide 5). At the middle of that intersection are our patients. We should always remember that this is all coming about for the betterment of our patients.

(Slide 5)



What I want to talk a little bit about is cyber security. You no doubt heard the headlines last night that there was a major hacking incident with the United Kingdom National Health Service.

I have been talking about the cyber security of healthcare data for a long time. There are two major threats to healthcare data that we can see. One is the criminals, particularly in the United States, that are trying to steal healthcare data, and what we find in the United States is that this health information and stolen credit cards are being sold on the black market.

If a credit card sells for one dollar in the criminal marketplace, a health record sells for 50 to 100 dollars in the same criminal black market. The reason is the criminals use the information and health record to create a false identity. Using this false identity, they can then perpetrate very extensive financial fraud. They take the false, created persona that they crafted from healthcare data and commit financial fraud, such as taking out loans, creating credit cards, and buying boats or houses. This seems to be a problem that is more focused in the United States than in other countries because of the way our financial system works in the United States.

However, one problem that we are seeing everywhere in the world that differs from information theft, is ransomware. This is actually what happened with the National Health Service over the past 24 hours. With ransomware, what happens is that the criminal elements invade a computer system and then create some sort of a program that encrypts and locks very critical files inside the computer system, so the computer system will not

work because their files are locked.

The ransom part is that the criminals will not unlock the files or give you the key until you pay them a ransom. This is a problem everywhere in the world, and that is what we are seeing with the NHS today. My company does a lot of work for the NHS, so I have information about this issue. It looks like the attack that just happened in the last 24 hours was not actually targeting the National Health Service. It just happened to get into the National Health Service, and that is why it is grabbing all the headlines, but many people believe it probably started in Spain with an attempt to attack the telephone system there.

So, we are seeing this wave of attacks, and what usually happens is a small piece of software we call “malware” is embedded in an email and then somebody inadvertently clicks on the bad part of the email, which launches a ferocious malware program into that computer and locking down the files whether they be pictures, documents, or files, it locks them and then the criminal demands a ransom to unlock it. This is something we all have to be very mindful of, and very vigorous in protecting against.

Another point about cyber security is that our patients expect us in healthcare to continue to be the good data stewards of their healthcare information. Patients give us as physicians very private and confidential information because they know by doing so we can help them improve their healthcare and maintain their health. However, they will become very uncomfortable giving us information if we fail to continue to be good data stewards of that information because patients have seen that financial information has shown up inappropriately on the Internet in the past.

Patients also know that if a credit card shows up on the Internet that it is a problem. But you can undo the problem. It takes a lot of work—it might take a year or so—but you can undo the problem if your credit card shows up on the Internet. If your diagnosis of diabetes or HIV infection or the fact that you take psychiatric medications shows up on the Internet, that cannot be undone. That is what

(Slide 6)

**Historical perspectives**

The WMA has been concerned about health data for decades.

- As early as 1973 in a “Resolution on Medical Secrecy” addressing Computers and Confidentiality in Medicine at 27<sup>th</sup> General Assembly [GA] in Munich
- GA in Venice in 1983, short statement
- GA in Washington, DC 2002, extensive declaration
- The WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks approved Nov 2016 by Taipei General Assembly



we call a bell that you cannot un-ring: once the bell rings, everybody hears it.

Patients are very mindful and fearful that their very personal and confidential information may show up on the Internet, and they are expecting us as physicians and healthcare workers to do everything we can to protect that very private and confidential information that they have provided us. So there are many reasons why we need to improve cyber security in healthcare: because of the false identity and ransomware problem, because of the privacy problem, and because of the security and trust that our patients give us to keep their confidential information secure and private.

### WMA Declaration of Taipei

I want to talk about the Declaration of Taipei. We as the World Medical Association thought this declaration was important for physicians to talk about the ethics of collecting health databases and biobanks going forward (**Slide 6**). It was a very lengthy and detailed project, and as I said, the WMA has been concerned about this for a very long time. As early as 1973, there was a resolution on medical privacy by the World Medical Association, and then in 2002 there was a very extensive declaration on the digital information we are starting to collect on patients. We felt that this declaration needed to be revised in 2017.

The revision process started back in 2012, and it took almost four years to complete these very difficult and challenging ethical guidelines. We had a lot of input; we had open consultations in Copenhagen and Seoul. We had another open consultation during 2016, and we had a committee com-

prising members from all around the world, including the JMA, who provided a very rich range of perspectives on what their national concerns are about privacy and the security of health information. These efforts resulted in the Declaration of Taipei.

A couple of things for us to think about when we look at this: one, which was already touched on in the last lecture, is the question of what is identifiable information and what is de-identified and anonymized. The problem today is that with all the ways available to link information, we probably cannot completely anonymize or delink all the information. This is particularly true when we have genetic information about individual patients, as that is a very specific fingerprint that would identify individual patients.

Since we probably cannot completely anonymize or de-identify information with today's technology, we also need to think about what we have always traditionally thought and relied on—that if we pool all the information and remove all the labels it is okay, the information cannot be linked back to a certain patient or individual. This is not true anymore.

We also have to think about consent. We are very comfortable in medicine about getting informed consent from our patients. But in the world of databases and biobanks, where we may collect information today in 2017 but not use it for another 10, 20, or 30 years, the consent issue is very different. If I obtain the consent of my patient in 2017 to use their information or their blood, what happens if I discover a new purpose to study their blood or information in 20 or 30 years? How do I get their permission in 2017 for something that may happen in 20 or 30 years' time? This is a very challenging issue that we need to deal with.

What we said was the cornerstone of how we in medicine should handle this, is through research ethics committees, because almost every country has a process where medical, ethical and legislative experts come together and create research ethics committees. These committees set a sort of golden standard on which everyone in healthcare

relies to make sure that we are taking care of their ethical and scientific concerns regarding using data or conducting research. So we relied on the research ethics committee to unravel some of these very sticky problems because we cannot possibly anticipate every problem in our Declaration of Taipei.

Now, it is worthwhile saying that there is a pretty broad spectrum of research ethic committees across the world. Some countries have very developed research ethics committees, while those in other countries are not quite as developed, and so we recognize this and we put it down on paper as well.

We also think it is important to think about governance. How is this data being managed, whether it be fluids, genomic data, or digital information? How is it going to be handled; who is going to be in charge; and who is going to be held accountable for the management of this information? So we think it is important to consider these issues going forward that go beyond the ethical considerations of health databases and biobanks.

With biobanks, again, this is not just information but also tissue and fluids. Many of the same issues come up as with digital information, but there is an additional dimension when you talk about tissue, body fluids, and blood.

We were especially concerned about the handling and transfer of materials. I can tell you that from the perspective of Africans, based on their long history of being exploited, they are very concerned that people or countries or industries will come to Africa and take advantage of the African people's poverty and maybe lack of sophistication and they will exploit their population, particularly in taking biological materials. That is why it was important that we state in our Declaration to be on guard against the kind of exploitation that African people are concerned about.

Next is security; we already talked about this. It is very critical that our patients know that we are continuing to be the best stewards possible of their data and keeping it secure and private.

## Instead of Looking for a Needle in a Haystack

Let me switch gears to say that we are very excited about the current level of technology and what we can do with the data once we have all the information collected. I work for a big technology company with 170,000 employees worldwide. We do 25 billion dollars' worth of business each year, and so we are developing very exciting technologies for looking at new methods of analyzing data.

For example, in the old world of analysis, we would take a hypothesis and test it against the data. I have a hypothesis, drug A is better than drug B, let me ask the data.

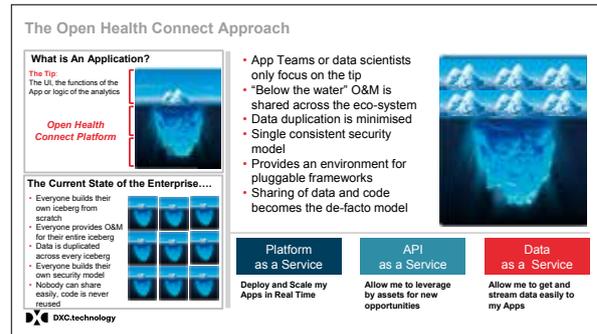
In the new world of analytics and business machine learning, we believe we are going to have the data speak to us, telling us things through associations and patterns that we would never think to even ask the data. This is an exciting new opportunity and it is like instead of looking for a needle in a haystack, making the needle show itself out of the haystack.

This method will be much faster and simpler than going through the entire haystack looking for the needle. This is one of the technologies we are very excited about.

## Open Health Connect Approach

Another issue is that we need much more interoperability of the data that we have. We need data to flow more like water and less like bricks. All of us that have worked in information technology have experienced times when moving data from one place to another was a little like moving bricks—very heavy, very slow, very laborious—but it would be much better if data flowed like water through a pipe.

One project that we are currently working on is called “Open Health Connect”. Data scientists are only focused on the top of an application, the “tip of the iceberg”—the part you can see above the water, but below the surface there are also elements such as middleware and infrastructure (Slide 7).



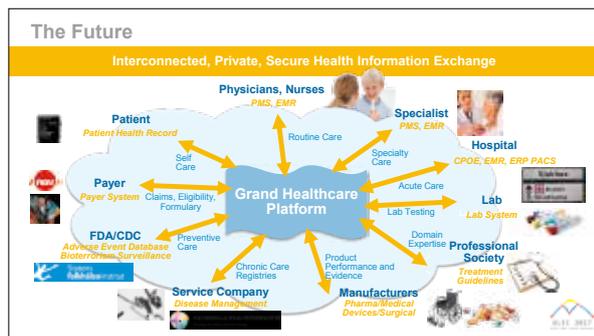
The problem we have in healthcare today is that everybody is building their own iceberg. They are building all these icebergs and repeating this bottom part (below the surface). What we think we need to do is pool our resources and have a much more common base under the surface of the water. We can still have very individual tips that are visible above the water’s surface, but we should not be rebuilding our icebergs underneath the water over and over again.

We are very excited about a new technology that would build a single infrastructure underneath the surface of the water but still allow the individual tips above the surface to be used. This is a process we call “Open Health Connect”. It is a lot like where we are today with cloud computing, where everything gets done as a service. Platforms as a service, what we call API (that is, “application process interface”) as a service, and then is how you connect in and out of systems, with data as a service.

## Grand Healthcare Platform

So again making the data more fluid, less like bricks, is important. We are very excited about this concept of creating a single iceberg under the water’s surface with multiple tips above the water. Where this all comes together for me as a physician who has worked in health IT for nearly 20 years is when I think back three years ago to when I was standing in this room and talking about my views on health information technology—and I may have shown these slides, so my apologies for those of you that were here three years ago—but I still believe this is where we are heading: we are

(Slide 8)



going to build a Grand Healthcare Platform in the center for healthcare (Slide 8).

This platform will be a virtual pool of information. It will not be one hard drive, one big data center that we are going to put everything into. The data will be federated, which means that it will stay where it was created. We are not going to put it all in one place. But once we have this virtual pool of information at the center for healthcare, everyone participating in healthcare will be able to contribute to and extract information out of the pool.

Everybody around the circle—physicians, nurses, specialists, hospitals, laboratories, medical societies, manufacturers, governments, payers, patients, and citizens—will all contribute to and extract data from this pool of information. I think we are very quickly heading towards this system, and these little gold arrows are very secure pipes, with strong security for going in and out of the pool. This is where we are heading. I am excited about this future because the pool of information is going to become very rich with health databases and biobanks adding to it.

## Better Information for Better Healthcare Decisions

Finally, it is my belief that the role of technolo-

(Slide 9)



gy in healthcare is to provide better information for better healthcare decisions (Slide 9). As I said, I am a physician who loves technology but not because I like the bytes and bits and boxes. I do not write code at night; I do not make applications on weekends. I am simply a doctor who wants technology to help me take better care of my patients. The way I think technology will help me take better care of my patients is by providing better information for making better decisions.

Everybody in healthcare will make better decisions with better information. Patients, doctors, governments, payers, and researchers will all make better decisions with better information. It is the role of technology to deliver the right information to the right person at the right time. That is the really exciting promise of what we are talking about in health databases and biobanks.

I want to again thank the Japan Medical Association for your kind invitation. It is always a pleasure and a privilege for me to travel around the world and hear what is happening in healthcare from the frontlines. Thank you for your attention. I hope this information will be helpful, and I am happy to answer any questions in the Q&A session.

● Lecture 2 ●

# Personal and Private Big Data: Genomes and Health Records

Ju Han Kim

Professor, Seoul National University College of Medicine



I was previously here 13 years ago, so today is my 13-years-later presentation, with a slightly different topic about health data. The title of my talk is “Personal and Private Big Data”. I use the word “personal” because, as you all may have seen in the previous two lectures, although the data has great value, it also has risk, and we need to deal with that. The reason why we have risk is that the data is personal—and even private—so we may need to develop a strategy to deal with both these complex, contradicting issues.

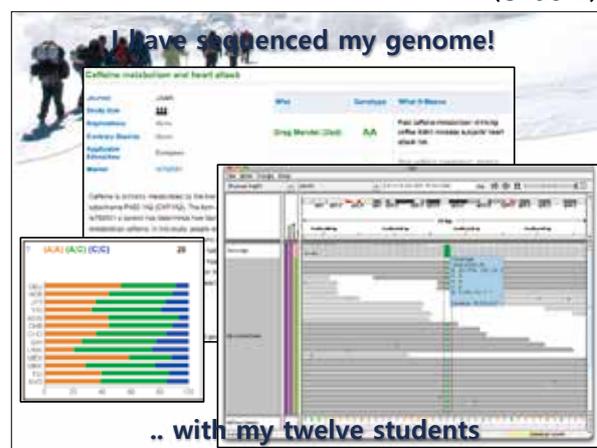
I will start by briefly introducing the complexity of genomic data, on which my research focuses, and then explain our pilot system, which is intended to orchestrate balance between the risks and benefits of using this very sensitive and very vulnerable data.

For this reason, the title includes “Genomes and Health Records.” If I could add one more type of data then it would be LifeLogs, which are being used by many members of the public. For the first time in the entire history of medicine, patients themselves have started to generate and use their own data using lifelogs. Thus LifeLogs should be added to this complex system.

## I Had My Genome Sequenced!

I will start with my personal experience concerning my genome. Genomic data is extremely sensitive. As was shown in previous talks, genomic data cannot even be anonymized. It is identifiable, plain and simple. You cannot even change

(Slide 1)



your genome sequence at all because it is in you.

Genome data contains even more information than your entire medical record, especially when you are in a healthy state. It is valuable, and the cost was initially very expensive but is now below a thousand dollars, so there is no reason why we do not integrate this genomic data into patients’ health records. But it is very tricky.

So I decided to sequence my genome in 2011, when it was still very expensive, and I gave my genomic data to my students for them to try to find out something about me from my data. The first genomic site that was interpreted was Chromosome 15 (Slide 1). They were all “A”s. So I have an AA genome type. The first step when you have identified one genome type from your genome is to link your genome type to your database.

Here is the population structure of AA genome type among Han Chinese in Beijing (HCB) and Japanese in Tokyo (JPT)•••, which represents my

ethnic group very well. This data says that when I am one third, my type of person may be found in one third of the whole population of my ethnic group.

You then link this data to some knowledge base and find that I am a fast caffeine metabolizer—which has been a well-known genome type for a long time—and then eventually you link this data to literature. One German article says that this type of person—the genome type, by the way is on the cytochrome A2 enzyme—is well-known to be a fast caffeine metabolizer. They have done some clinical research and have found that this type of person, because they can metabolize caffeine very well, high levels of caffeine consumption does not increase their cardiovascular risk. So at least the test had some positive implications in that respect.

I am encouraging all my students to sequence their genomes, now that it is affordable. I am going to give you one more interesting example concerning my genome which is both terrifying and valuable, as well as revealing (Slide 2). I have found that I have Coagulation Factor 10 (F10) inhibition. Coagulation Factor 8 deficiency is the cause of hemophilia. F10 deficiency is extremely rare; there have been only two cases reported in the world.

But I found that one copy of my F10 has been lost. This type of inhibition is loss-of-function inhibition. So I lost one F10 copy. If I had lost both copies, I could not have been born, because bleeding could not be stopped at all. So it is okay, I do not have any bleeding tendencies. But one of my laboratory physicians took me to her lab and measured all factorial activities. All my blood coagulation factors are okay—showing 100% function activity—except for F10, which shows 67% of normal activity, which is below the minimum limit (which is 74 at my hospital), and my prothrombin time (PT) is 12.3 seconds, which is above our upper limit for PT.

It is clear at a molecular level and functional level as well as physiologically that I have thin blood. So my bleeding time is longer. What the implication here is, is that I may have evolved bet-

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- ✓13M prescriptions in the US
- ✓1/167 has such deleterious DNA variant.
- ✓Low F10 score revealed both poor F10 function (67%) and a 'causative' DNA variant for a founder of CIPHEROME INC.

Factor	Fx (%)	Normal Range
FactorII	100%	84 - 130
FactorV	113%	63 - 140
FactorVII	127%	72 - 141
FactorX	67%	74 - 146
FactorVIII	87%	50 - 194
FactorIX	132%	48 - 100
FactorXI	123%	72 - 153
FactorXII	68%	44 - 142

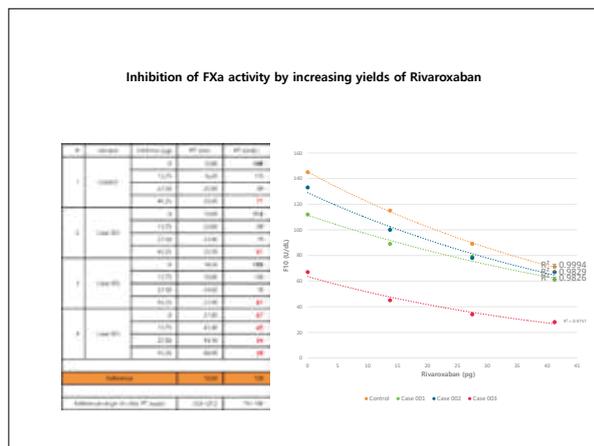
PT	12.3 sec	9.8-12.2
APTT	34.9 sec	26-35.3
Fibrinogen	335 mg/dL	180-360

ter than you because today hypercoagulability is more of an issue than bleeding tendencies. Many of you may have to take anticoagulants to prevent you from prothrombin events, especially in old age. So slightly lengthened bleeding-time is not a health risk; rather, it could be a benefit.

What happens if I take a new oral anticoagulant drug such as Rivaroxaban (Xarelto), which is a direct F10 inhibitor? If I take a F10 inhibitor, it will lower my functional activity to 30, which means that I could be killed at any time. It is a terrifying risk. Rivaroxaban (Xarelto) is a blockbuster drug which has 13 million prescriptions in the United States alone. I have researched the lawsuits against this drug on drugwatch.com. You do not want to see this kind of TV ad: the Waldman Smallwood law firm called for those who have experienced bad side effects from taking the Xarelto drug to contact them. For this one anticoagulant drug, Rivaroxaban (Xarelto), there are currently 7,400 lawsuits filed, and they will be resolved this year in Louisiana court. Taking such drugs could be very dangerous.

The frequency of my type of F10 inhibition is one in 167. So within this audience, at least one person may have a similar problem as me, which means about 760,000 people in Japan—not a small number. One interesting thing is that the indications for the prescription of this drug have nothing to do with coagulopathy; rather, the main prescription indication is atrial fibrillation for elderly patients to prevent thromboembolic events. So people who are older than 80 have an almost 20%

(Slide 3)



chance of having atrial fibrillation, and so their physician will prescribe this drug to them and one in 167 will be killed without anyone knowing what has happened. I posted a message on my Facebook page to all my physicians saying, “Could you prescribe me an F10 inhibitor drug if you knew my genome type?” No one answered.

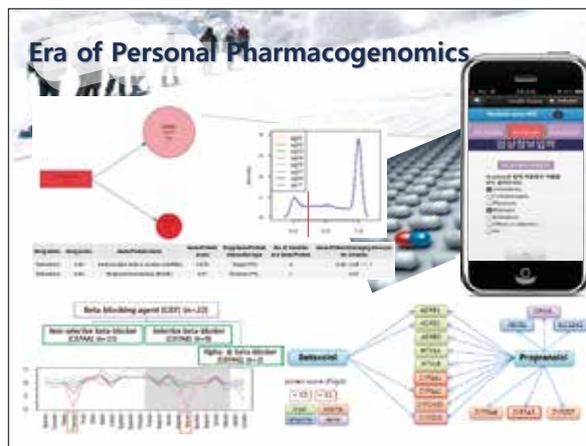
It was an exercise; I do not conduct full-blown experiments on myself or others. The functional activity of others who took the drug fell from 100 to 60, which is the therapeutic target for functional activity while the drug concentration is increasing to the therapeutic level (Slide 3). My functional activity level started at 67 and fell to below 30, which means the drug could be toxic to me.

Regarding adverse drug reaction (ADR), which is the fourth leading cause of death in the United States, there are 2.7 million severe adverse reaction cases in the United States alone, from which 128,000 people may die, and the additional costs of these drug side effects on par with the cost of cardiovascular disease. It is a huge problem. However, we may be able to manage this problem by knowing interpersonal variabilities.

### Era of Personal Pharmacogenomics

Slide 4 shows examples of 22 beta blockers; the lines are the scores for my students and me. This particular female student, the red line, shows very low scores for Propranolol non-selective and Betaxolol selective beta-blockers, which means she has a mutation on her cytochrome 1A1, 1A2, and 3A5, which are the major enzymes for Pro-

(Slide 4)



pranolol and Betaxolol. But her scores for many other drugs were within the normal range of scores. Why would you prescribe this particular drug to this subject if you knew she has a particular mutation on these pharmacokinetic genes?

I have created a smartphone app for her and that shows her genomic sequence and CCR (Continuity of Care Record) and recognizes prescription sheets and checks them for signs of risk for her to show to her physician. I have said to her, “Wow, these are very important pharmacokinetic genes related to more than 200 drugs, so what happens to you?” Her answer was, “Professor, I take just half of the drugs I am prescribed because I have experienced so many side effects.” After a pause, I replied, “You did a good job.” This experience is actually changing my beliefs because it is an issue concerning compliance. Patient should take their drugs according to their physician’s instructions or prescriptions, but in cases such as this, we may have to be more cautious.

Interpersonal variability is a very big issue for big data. If you integrate old personal big data, you can tailor your diagnosis and therapy to individual patients. Interpersonal variability is something that has not been integrated into current medical practices.

### LifeLogs

I have briefly touched on the importance of the genome in this era of “precision medicine” (Slide 5). As I mentioned at the beginning of this talk, LifeLogs will be a problem. Patients, for the first

(Slide 5)



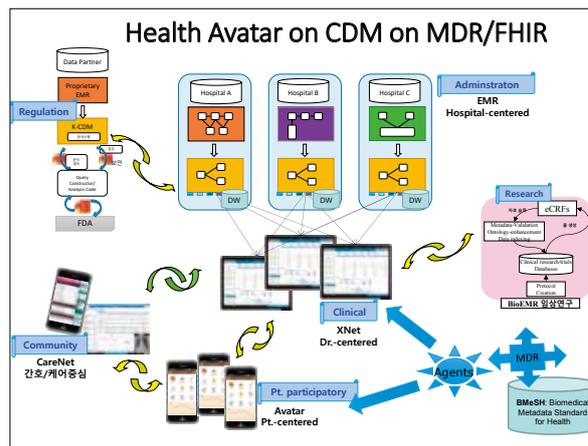
time in medical history, have started to collect their own data and let the data work for them. The types of data are ever-increasing and should be integrated into patients' health records very soon. But LifeLogs are outside the medical system. As doctors, we do not have control over LifeLog data.

Here I have a question for all of us. My LifeLog works for me at my cost without any preservation. For the first time in the entire history of medicine, the patients themselves have started generating their own data. Before that, doctors created patients' data on their behalf. What about our health records? Health records are stored in our EMR system; they sleep for long periods of time and are only awakened when the patient visits their physician's office. Health records then work for the patient for a short duration—of course, in a very efficient manner—and are then closed and sleep again 24/7. I would like to make health records alive, make the medical data inspire and work for the patient 24/7.

Genomic data is even more complicated. There is no way to store your genome data. You cannot store your genome data in one particular hospital because you cannot see or use the data when you are in a different hospital. But you cannot distribute all of your genome data to many institutions because it contains very sensitive information, like mine does. It is inherently identifiable, and it is not just personal or private data, it is also family data, so it is shared.

Actually a son of Nobel laureate, James Watson, his assistant, has filed a lawsuit against Wat-

(Slide 6)



son because he made his own genomic data public, and the son's argument was, "You and I share half of the same data. You do not have the right to release my data." That is the reason for the lawsuit. So genome data is extremely tricky to manage in our healthcare system.

### Health Avatar on Common Data Model

I observed two themes in the first keynote speech by Dr. Yamamoto. One is the centralization of all healthcare information data in a single repository. The other is the creation of a distributed system which was a sentinel system for Japan. We have a similar system K-Sentinel, and we have created a Common Data Model from different hospitals, although different hospitals have different data structures (Slide 6). When we supplied the Common Data Model, named K-CDM, they transformed the data into a Common Data Model that is currently used in 12 hospitals and that can be used for pharmacovigilance surveys, which are conducted for governmental use to ensure drug safety. This medical, EMR system serves hospital presidents and administrators. However, I realized that as yet there are no, or very few, systems designed to serve physicians and patients themselves.

We have created a physician-centered application. While the EMR system is an institution-centered information paradigm, we would like to create physician-centered information for each different specialty, such as cardiology and nephrology, and then allow users to communicate

(Slide 7)



using personal devices such as smartphones. Physicians can create their own networks, and patients can create their own networks.

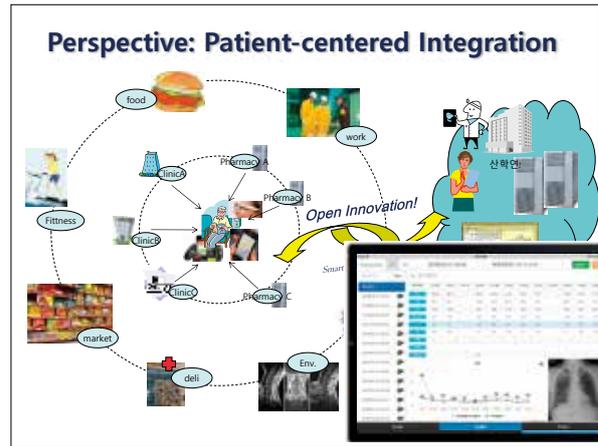
Currently, the paradigm is that physicians who are doing different jobs in different specialties have to use the same information system simply because they are working at the same hospital. But my opinion is that it might be better for physicians who are doing the same job—even if they work for different institutions—to share the same information system. We have divided the system into separate information systems for individual specialties and have linked these specialty-based clinical information systems to multi-centered clinical research. We would like to integrate clinical research and practice.

The big difference here is that there is no centralized repository at all. Each data type is located at the appropriate location for that data. Hospital data is located in the hospital: physician data is located in the physician's iPad app: patient's data is located and stored in the patient's smartphone; and so on and so forth.

There are two different paradigms. One paradigm is collecting all the data in a central repository and protecting it with very strong security devices, but data is not easy to protect once it is collected. It is my personal belief that the best way of protecting privacy is to keep data spread amongst different locations.

### Patient-centered Integration of Health

(Slide 8)



### Records

We have tested this kind of system and my project is “Health Avatar”, which involves making your smartphone your surrogate: having your avatar work for you, meet your doctor, see your nurse or pharmacist, and collect other second-hand information from the cyber environment (Slide 7). “Health Avatar” provides uniform access, enabling users to read and input personal big data, which is their medical record, genome, and LifeLog all integrated into the one smartphone app.

Patient-centered information is possible because you now have smartphones, which provide universal device programs (Slide 8). Each pharmacy or clinic can send you data concerning you and then this can be expanded to aspects of everyday life such as food, LifeLogs, fitness, and environment.

This type of integration enables you to undertake open innovation because it provides you with a unique, uniform view of your data structure, that third-party players such as artificial intelligence and decision support parties can provide through an open API to uniformly read and write your data to give you a certain service.

### Physician-centered Information System

Finally, as I mentioned, we found that physicians themselves need physician-centered information systems, so we first of all implemented this type of approach in the “Hemodialysis Net” (Slide 9). Hemodialysis is a good place to start because

(Slide 9)

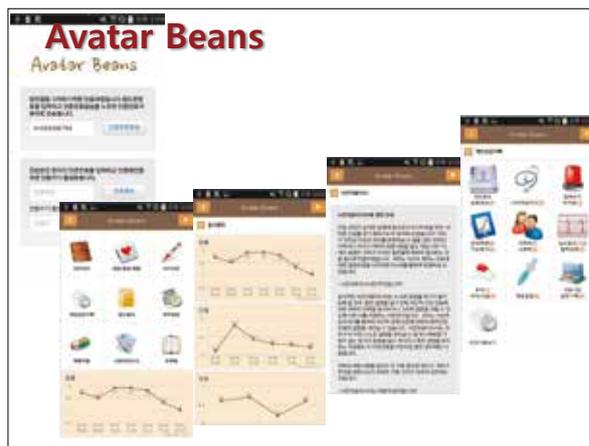


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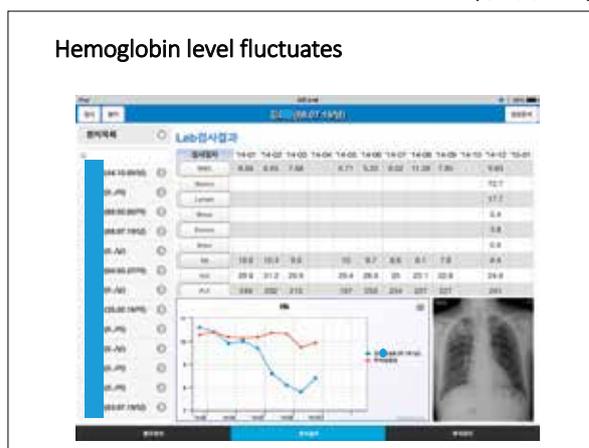


- 인제대 서울 백병원
- 인제대 상계 백병원
- 강원대 병원
- 경주 동국대 병원
- 건양대 병원
- 이대목동 병원
- 파티마병원
- 측주병원
- 광내과의원
- 을지대 병원
- 부산대 병원

(Slide 10)



(Slide 12)



the practice of hemodialysis is standardized all over the world. Patients visit the clinic two or three times a week; it is very data intensive; and it is a disease of the elderly, and so the healthcare costs for chronic kidney disease is ever-increasing. I heard that Taiwan spends 8% of health expenditure on hemodialysis. We therefore created a system to test this kind of paradigm.

Slide 10 shows the app for physicians. Physicians have all their patients' data, and each patient has their own data; physicians can send data information such as hemoglobin, potassium, and calcium—the most important information—to each patient and it will be displayed and managed by the patient.

We started three years ago in our own hospital, and currently we have 15 major hospitals using this system (Slide 11). The advantage of this is that medical staff can perform rounding with all of the information stored in this system and the information can be sent to patients and used by doctors in

making decisions together with their patients and so on.

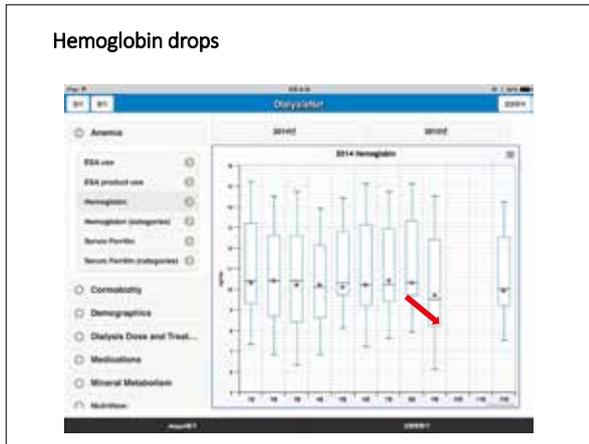
We have extended usage of this distributed app, so currently in South Korea, we have about 15 major hospitals and clinics using the app, which actually shares the same structure base as the Common Data Model for pharmacovigilance I showed you previously.

### Pharmacovigilance

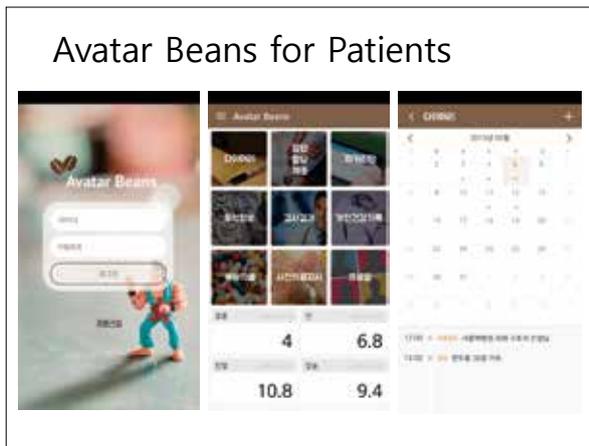
So the same system, same structure—which is a distributed one—serves two totally different proposes: for clinical practice, and for government-driven pharmacovigilance for drugs and infections. The advantage of this system is that you are able to manage the whole clinic. Individual patients' data can be compared to the average data of 100 hemodialysis patients, which makes it easier to persuade and educate your patient.

We have had experience with this. Slide 12 shows a drug's classification. Hemodialysis is the

(Slide 13)



(Slide 15)



most standardized practice, so the drug's classification provides standardization of all your analysis and displays your laboratory results, which include about 100 items.

We incorporated all these in the program, and one day a clinic found that average hemoglobin levels at the clinic had gone down, which doctors had never known to happen before the introduction of this kind of system (Slide 13). It was a big problem, so we researched every event that had happened at this particular clinic two years ago, and we found that a new drug had been introduced at around that time.

We did not have any evidence that the drug caused this kind of problem, but the salesman had said you have to wait for at least three or four months and so on and so forth; so the clinic just stopped using the drug without confirming a causal relationship because low hemoglobin levels were a disastrous condition, and hemoglobin levels went up again (Slide 14). It was a lesson for us:

(Slide 14)



(Slide 16)

### Colorful Clinical Avatars

- Clinical Problem-oriented applications
- ✓ Avatar Beans & DialysisNet
- ✓ Avatar Jr. & KidsNet
- ✓ Pink Avatar
- ✓ Avatar Gold & OncoNet
- ✓ Avatar Fit & ArthroNet
- ✓ PsyBase 2.0, Avatar BeWell & CareNet

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if you have big data that is managed well, you may be able to respond to a pattern of data without knowing the underlying reality.

We have created a system covering all these aspects and made the Version 2.0 look much prettier and so on (Slide 15). Gradually we have expanded this system from the dialysis unit to pediatric cancer, breast cancer (Pink Avatar), colon cancer, sports medicine, ArthroNet, and psychiatry, which is my specialty (Slide 16). We are attempting to reorganize our computing paradigm for each specialty-based, physician-centered computing paradigm. Eventually we will have a platform, and so we would like to orchestrate interplay amongst smartphones and iPad apps and servers. We have created a health avatar platform where you can plug in your personal patient's avatar—which is composed of your genome, your LifeLog, and your medical records, which are logged in—and the physician's system, which is also logged in, and they will interplay with a secure platform in a

(Slide 17)



(Slide 19)



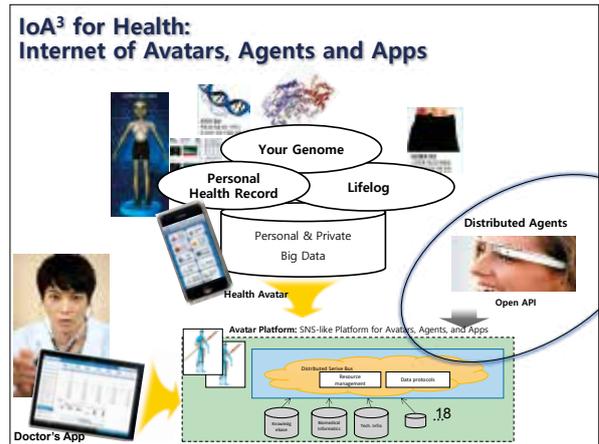
verifiable manner. Then, as I mentioned, third party players can provide intelligent clinical decision support apps (Slide 17).

### Internet of Avatars, Agents, and Physician Apps

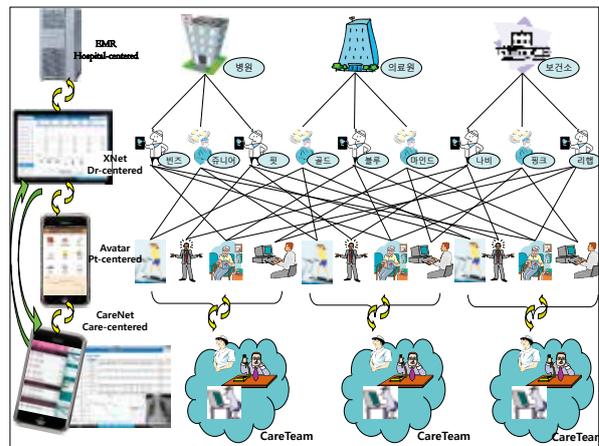
In imitation of IoT, "Internet of Things", I have named our concept the "Internet of A<sup>3</sup>": the Internet of Avatars, Agents, and physician Apps (Slide 18). Our aim is to create cyberspace counterparts of our activities in the real world. Agents can be supported by such programs, and we have already developed many (Slide 19).

In summary, hospitals have built their own proprietary systems, but these are primarily designed to serve their own institution. However, once a system is transformed into a common format, it can be used by government agencies without centralizing data, as in the Japanese central program (see Slide 6). In Korea, we call this system "K-Sentinel". From the managed data, you can pull out

(Slide 18)



(Slide 20)



clinically relevant data supported by data technology to build clinical and patient applications that can be uniformly connected based on this data technology.

We are trying to build a community-wide program, and I realized that we need another layer, which is for caregivers. Caregiver-centered information systems are also required. Clinical research about multi-centered information for each center can be supported by this kind of technology.

What I realized was that the current EMR system is merely an institution-centered information system, but not a system for all of us. It is not a physician-centered or patient centered one (Slide 20). One solution does not fit all. We need physician-centered information systems and patient-centered information systems, as well as community-centered information systems, in the era of personal and private big data.

Thank you for your attention.

● Lecture 3 ●

# Development of the Taiwan Health Information Network and Health Cloud

Heng-Shuen Chen

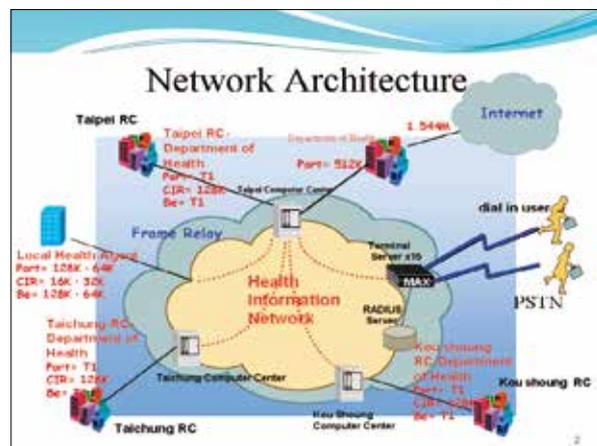
Assistant Professor, School of Medicine, National Taiwan University



(Slide 1)



(Slide 2)



## Development of Taiwan Health Information Network

To begin, I will give you an overview of the development of the National Health Information Network (HIN). In 1988, HIN version 1.0 was made for public health administration and health insurance management. At that time, there were only labor health insurance and government employee insurance schemes.

The National Health Insurance system started in 1995. In 1999, after the Internet became very popular, Taiwan started to develop electronic medical records (EMRs). Subsequently, with the aim of developing a medical image exchange center on the network, the HIN version 2.0 was introduced around 2000. In 2001, National Health Insurance IC cards were launched, and many Internet applications were later developed.

In 2008, the Ministry of Health and Welfare started the National Health Informatics Project.

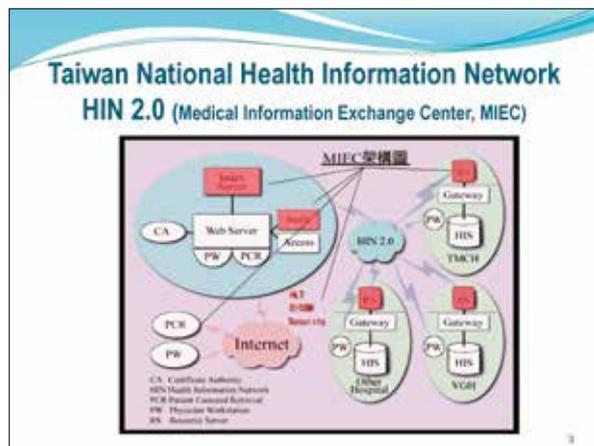
The purpose of this project is to return health information to citizens. Personal Health Records (PHRs) subsequently became a major issue in developing the national Taiwan Health Cloud (Slide 1).

In HIN ver. 1.0, for health insurance management, we had three major regional centers—in Taipei, Taichung, and Kaohsiung—and these centers were connected via network (Slide 2).

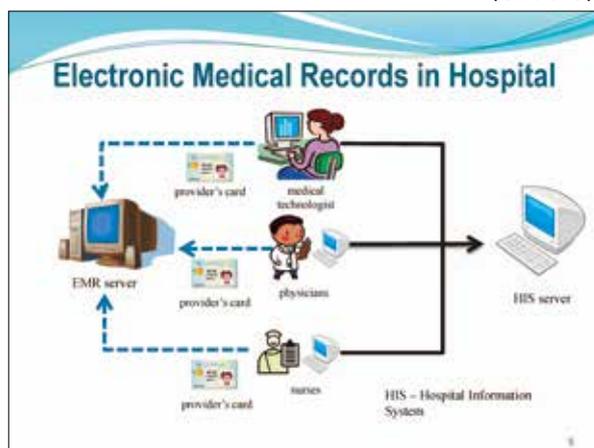
In HIN ver. 2.0, we incorporated EMRs and medical images. Medical information and images are stored on National Health Insurance Agency servers and are connected by virtual private networks. Other medical information application shared among hospitals and clinics is on the Internet (Slide 3).

At the National Health Insurance Agency, there is an Electronic Medical Records Exchange Center with an index server, and hospitals can connect to this exchange center (Slide 4).

(Slide 3)



(Slide 5)



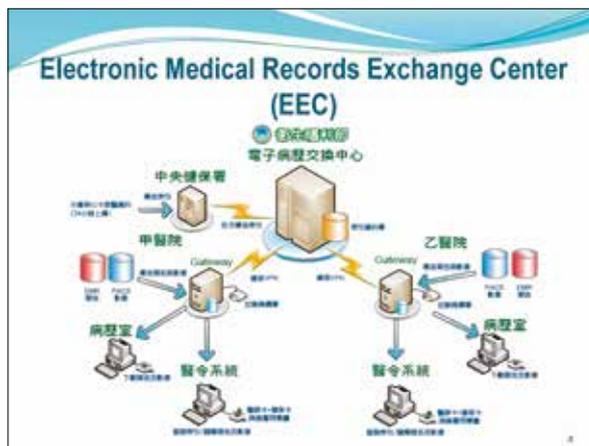
### Benefit of Electronic Medical Records

When a physician wants to retrieve a patient's medical records from another hospital, they just use their health provider IC card in combination with the patient's health insurance card. They obtain authorization to access the EMR and medical images from the other hospital (Slide 5).

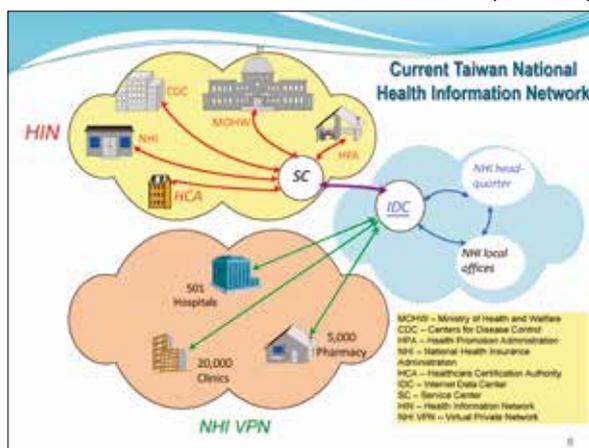
The health provider IC card is for not only physicians but also other healthcare professionals such as nurses, medical technologists, and even psychologists or nutritionists. If a health provider needs to input information into a medical document or make a medical record, they must use their provider IC card in order to make the electronic signature.

Slide 6 shows the current Taiwan National Health Information Network. There is a virtual private network (VPN), which is a cloud under the National Health Insurance (NHI). The Internet Data Center (IDC) connects hospitals and the National Health Insurance Agency. They are other

(Slide 4)



(Slide 6)



applications.

In the past, our medical records were paper, but now we use paperless, electronic document formats. For example, in 2014 the National Taiwan University Hospital created 160 EMR documents, eliminating the need for 8,017,120 paper pages (which pile up to a height of 110,214 cm), 175 square meters of storage room, and 800 laser printer cartridges.

There are seven stages of EMRs, starting from just automation and digitalization, then sharing within the same institution, and then sharing among different institutions. The highest level is sharing among different specialties. Patient-centered integrated data is provided.

Currently, the Taiwan Health Cloud Project is trying to integrate all the PHRs from different government agencies—the Health Promotion Cloud, etc., from the Health Promotion Agency; the Medical Cloud, which comprises different hospitals and clinics under the National Health In-

(Slide 7)



(Slide 9)



insurance Agency; the Disease Control Cloud; and the Care Cloud, which is for long-term care and disabled people. The care and services can be connected. This integration effort is still in the beginning stages.

### Taiwan Smart Healthcare

Smart healthcare uses Information and Communication Technology (ICT) to promote patient safety, medical care quality, and healthcare service efficiency. Patient engagement is becoming more complex in our rapidly aging society. The increased healthcare needs and lack of resources are forcing us to make some changes.

The advantage for Taiwan's smart healthcare industry is that we have strong ICT and good medical care. There is a huge hospital market: 100,000 hospitals globally, 500 in Taiwan, and 25,000 in China.

Currently we use automation and many e-prescription systems (Slide 7). We use many monitors

(Slide 8)



(Slide 10)



and robotics in performing surgeries. For both outpatient and inpatient chemotherapy, we use smart chemotherapy management (Slide 8).

There are many physiological data devices. Data can be collected by using compatible protocols. We have physiological data gateway, which is connected to the cloud and shares data among the care providers (Slide 9).

The previous speaker mentioned hemodialysis, and in Taiwan hemodialysis accounts for 8% of healthcare expenditures. It is very important to implement good hemodialysis management (Slide 10).

### Big Data + Open Data + My Data

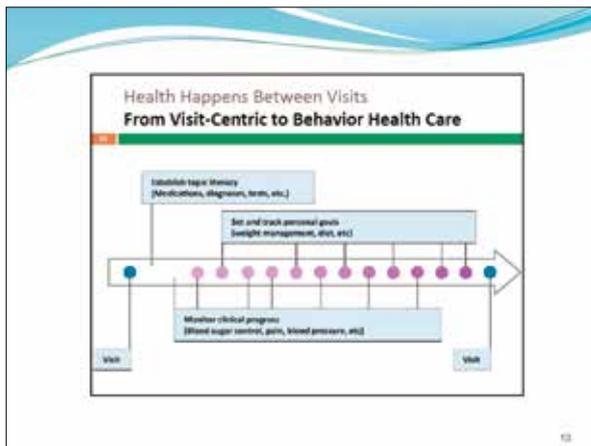
First, we need to collect all the health information and create big data. We then need to make this big data available to all healthcare providers and citizens. PHRs must become open data, then “my data”.

Here is an example of big data. In Taiwan, all

(Slide 11)



(Slide 13)



the hospitals need to provide their real time ICU bed information so that we can know in an emergency situation which hospital to send the ambulance to.

The future is ABCD, Analytics, Big data, Cloud computing, and wearable Devices. Alongside disruptive technology—the most innovative technology, according to McKinsey & Company—the mobile Internet, knowledge management systems, cloud computing, and the Internet of Things (IoT) are ranked the top.

Wearable devices are becoming very small. This one may be available on the market (Slide 11). It features many functions: emergency calls, fall detection, heart monitoring, and even sleep detection (Slide 12).

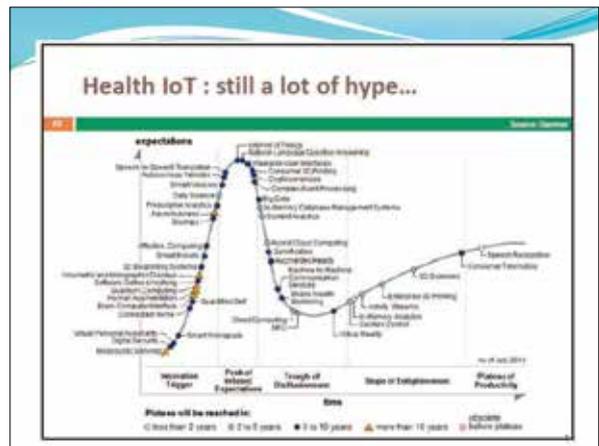
I myself wear a device here. You can see how I slept well last night because I was treated by the JMA president to a very good dinner—I can show you on my smartphone.

This device can be used between healthcare vis-

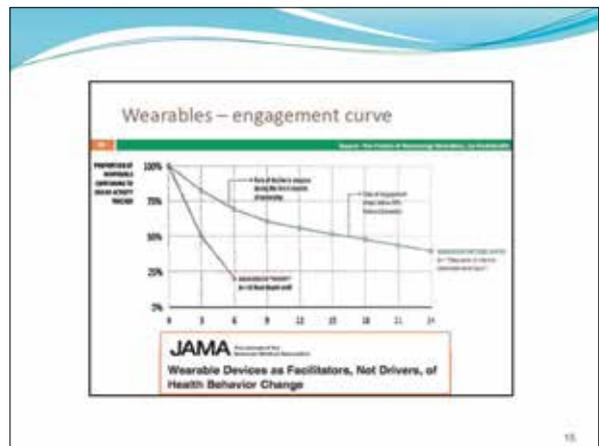
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(Slide 14)



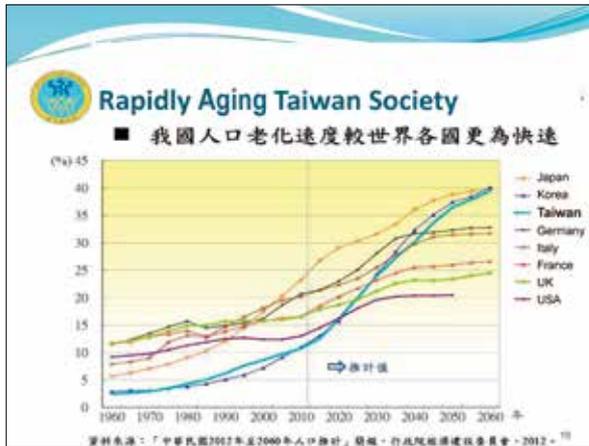
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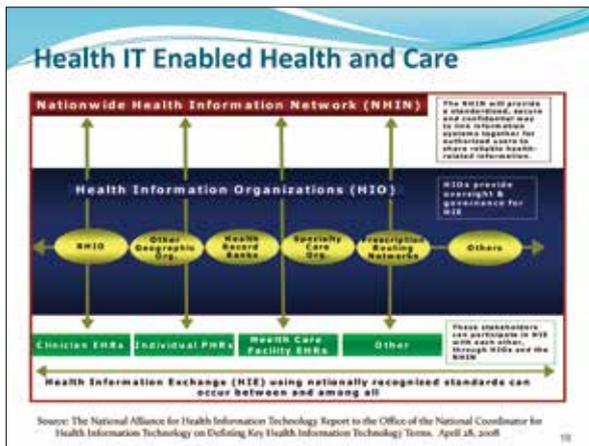
its. Usually for a chronic disease patient, I might see the patient once every three months. But what happens between these visits? We still need to make efforts such as lifestyle modifications or health education, and so this device can be useful (Slide 13).

There is still a lot of hype about the Internet of Things (IoT) (Slide 14). This innovative technology has several stages. IoTs are still at the peak of

(Slide 16)



(Slide 18)



expectations. Wearable devices are very useful (Slide 15).

### Personal Health Records in Taiwan

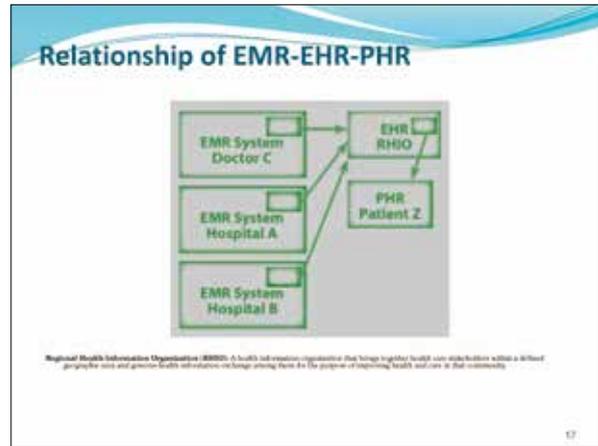
I will now talk about the elderly problem and the integration of long-term care into personal health records. In Taiwan, aging of society is progressing very fast, and will peak in 2060. These are the problems (Slide 16).

In 2000, 10% of the elderly accounted for 25% of total healthcare expenses, but by 2025, they will account for more than half of total healthcare expenses.

PHRs can be retrieved from electronic health records (EHRs), which are patient-centered. EHRs are collected from different hospitals and clinics, while electronic medical records (EMRs) are kept within the one institution (Slide 17).

At a national level, PHRs can be retrieved and collected from different government agencies or the private sector. With the National Health Infor-

(Slide 17)



(Slide 19)



mation Network (NHIN), useful applications for PHRs can be developed (Slide 18).

We currently have two kinds of PHR: My Health Bank and PharmaCloud. Citizens can use their health insurance card and go to the website to download their own personal health records from the National Health Insurance Agency (Slide 19).

Physicians can also access a patient's PHR when he/she visits the clinic or hospital. The provider IC card, used in combination with the patient IC card, can access not only the patient's health records, including medication records and laboratory examination results, but also medical images.

### Development of the Community Medical Group

In 2000, we developed the Community Medical Group (CMG), and in 2001 we further developed a Community Healthcare Information System for this group. In 2009, we developed the PHR Working Group of the Taiwan Association of Family



Medicine (TAFM). I was the chair of this working group. In 2016, we developed a multi-dimensional consent structure.

In September 1999, a great earthquake struck central Taiwan. After the disaster, we found that all the health records had been destroyed and we needed to rebuild.

To reform the community health system, we developed the CMG to restructure the destroyed health system. We used family doctors and the Healthcare Information System to achieve this purpose.

A CMG comprises 5 to 10 primary care physicians in community hospitals, and its function is not only providing medical care, but also providing a 24-hour call center for consultation services, as well as integrating medical care with community medical education and sharing care among primary care physicians and community hospitals. Medical centers and medical schools support the system.

Our Community Health Information System has clinical, academic, public, and private databases for providing health counselling, emergency medical care, and appointment registration. Citizens can list their family physicians. Under this system family doctors can share health information with other group members (Slide 20).

This system now has over 400 CMGs with over 3000 family doctors throughout Taiwan. They are not all family medicine doctors. About two-thirds are specialists in other fields and are practicing primary care. Such doctors can get together and



form a CMG.

In this information system, we have the prototype for the PHRs, including inpatient, outpatient, emergency care, medication, and preventive service records. We also have the electronic referral system. This is a bi-directional referral system, so primary care physicians can access the information when the patient is admitted to hospital or referred to a specialist.

The PHR prototype, which was introduced in 2000, includes demographic data, a chronic/active problem list, medication, food allergies, outpatient care, hospitalization, emergency service visit records, consultation and referral records, and immunization and preventive service records.

## 2010 Personal Health Record Guidelines

The TAFM PHR guideline was created in 2010. These have a multi-dimensional guideline structure. The first dimension is the natural history of disease. This is related to preventive medicine. In the beginning there were three stages, but we expanded it to four stages (seven levels) (Slide 21).

We provide a continuum of healthcare in different healthcare settings, from preventive to emergency, acute care, sub-acute care, long-term care, and terminal care such as hospice care. The third dimension is holistic care: bio-psycho-socio-spiritual. The fourth dimension is related to long-term care. Assisted living includes six categories. Other dimensions include age, sex, and risk factors.

These are the 4 stages of preventive medicine

(Slide 22)

### Natural History of Disease Stages and Levels of Preventive Medicine

Susceptible		Preclinical	Clinical	Disable	Terminal	
Primary (Non-diseased)		Secondary (Subhealth)	Tertiary (Diseased)		End (Death)	
Level 1	Level 2	Level 3	Level 4	Level 5	Level 6	Level 7
Health Promotion	Specific Protection	Early Diagnosis Prompt Treatment	Limitation of Disability	Rehabilitation	Palliative Care	Bereavement Care
Nutrition Exercise Weight Smoking	Vaccination Occupational protection	Screening Periodic health exam	Chronic Disease Control	Physical therapy Occupational therapy	Hospice care	Psychosocial and spiritual Support

(Slide 24)

- ### Holistic Care in Community
- 1980 George Engel biopsychosocial model
  - **Holistic Health Care**
    - Client Centered
    - Preventive to Palliative(Hospice)
    - Holistic Approach(Bio-Psycho-Socio-Spiritual)
    - Whole Community (Population)
    - Concept of Family Medicine: Comprehensiveness, Continuity, Coordination, Accessibility, and Accountability

(Slide 22). We added the terminal stage (end-of-life care, palliative care, and bereavement care).

For the continuum of healthcare, we use IT technology to provide telehealth or remote monitoring (Slide 23).

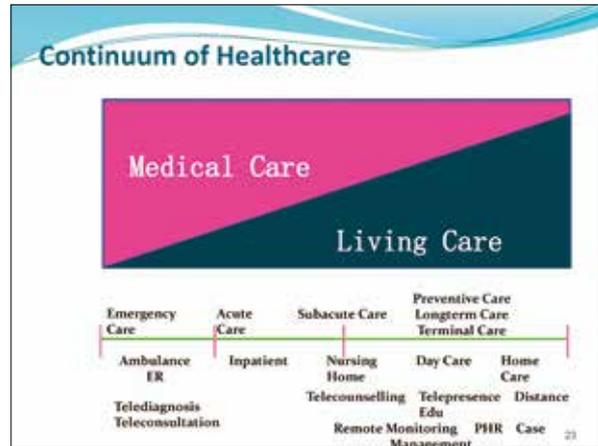
Holistic care is patient-centered, involves the whole community, and is based on the concept of family medicine (comprehensiveness, continuity, coordination, accessibility, and accountability) (Slide 24).

Assisted living has six categories. There are many assisted living services and they are incorporated into our new long-term care 2.1 programs (Slide 25).

### Puli Christian Hospital

Currently I work in the center of Taiwan. Our hospital' service zone covers 9% of the area of Taiwan with only about 0.7% of the population; the region has a high altitude and an aged society. This is a relatively closed community. I just moved

(Slide 23)



(Slide 25)

- ### Assisted Living
- Food: meal prepare/delivery
  - Clothing: dressing, laundry
  - Housing: elderly apartment facilities dormitory/hotel room, toileting/bathing assisted facilities, shared living room/kitchen/dinning room, beauty parlor
  - Transportation: transferring, escorts to meals and activities
  - Education: school of wisdom, volunteer training
  - Recreation: social/health activity program music /arts performing,

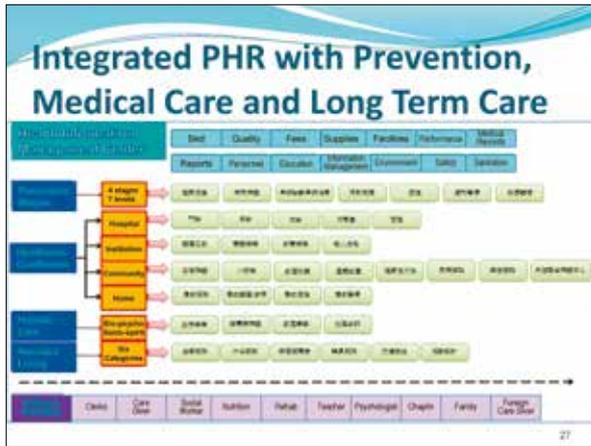
(Slide 26)



to this hospital last year. I want to become a grass roots person to develop a bottom-up healthcare information system in this area (Slide 26).

In our current design (Slide 27), we have the Health Information Management Center to cover different subsystems in four dimensions: Prevention Stages, Healthcare Continuum, Holistic Care and Assisted Living. We have different settings and different personnel. Different personnel pro-

(Slide 27)



vide different services, and so they need to use this kind of system.

As a hospital, we have an advantage because we are the only regional hospital and the biggest hospital in the area, and we provide a very wide range of services, including mobile clinics and long-term care. We can incorporate all the services you can imagine.

Regarding the future prospects for PHRs, PHRs have empowered the engagement of patients and members of the general public in their own health promotion and management. With the advance of wireless networks, wearable biosensors, and infor-

mation technology, we can develop health clouds integrated with community medical groups and integrated delivery systems, which will be the beginning of a capitation system in the future.

## Conclusion

What is a capitation system? We now have a new law called the National Health Insurance Law. Article 44 of this law states: “To promote preventive medicine, implement the referral system, and to improve the quality of medicine and treatment, the Insurer should draft the family physicians system. The benefits of the family physicians system should be paid out on a per person basis”.

This is the “family-doctor-system-per-capita”. The capitation payment system is included in the law. In future, we hope to provide comprehensive, continuous, and holistic healthcare through primary care family doctors in communities.

That concludes my talk. Thank you very much for your attention.

● Lecture 4 ●

## Health Data: Its Protection and Better Use for the Public and Patients

Norio Higuchi

Professor of Law, Musashino University Faculty of Law



I would like to begin by mentioning the two things I felt when listening to the experts who have given lectures here so far.

As Professor Yamamoto said, ICT development in the healthcare sector in Japan was relatively advanced until the year 2000—perhaps it was more advanced than in other countries. After 2000, however, the tides changed and so did the situation. In fact, the lectures by Dr. Wah of the United States, Dr. Kim of Korea, and Dr. Chen of Taiwan have substantiated this, and it made me feel that Japan has to make a stand now. Particularly in Taiwan, where not only is there a universal health insurance system similar to that in Japan but also a community-based care system has already been established, Dr. Kim reported that the information exchange for this community care is in progress and a form of care called “assisted living” in healthcare is being built. Obviously, a system for sharing information is necessary for long-term care, and a more personalized care and help for each individual is being built. I feel that there is so much more that Japan can learn from Taiwan as we work on promoting our Community-based Comprehensive Care System.

Another thing that left a strong impression on me was the cause of the delay in health information technology (HIT) in Japan. I taught law for about 40 years at law schools, and Japan was an advanced nation in the HIT field until around 2000 or so, but has considerably lagged behind in the last decade or two. I was very disappointed to

learn that the law, not the delay in technology development, was perhaps involved in the delay of HIT development in Japan.

I felt that HIT, the law, and the public awareness are all important, and all three need to be promoted to build a health information system.

### **From my Experience: Health Information Technology (HIT) is the Key**

I would like to mention a few things I have experienced. This is an anecdote—I have a friend named Murray Katcher, who is a very interesting man. He is a pediatrician, and although I believe he is already retired, he was a professor at the University of Wisconsin. When his friend became the Governor of Wisconsin, Dr. Katcher served as his Chief Medical Officer for some years as the second highest position in governing state health and welfare, a position similar to the vice minister of the Ministry of Health, Labour and Welfare of Japan (MHLW).

I visited Wisconsin for several research projects, and I had an opportunity to ask him various questions directly. It just so happens that shortly after 2000, when I was involved in a medical accident investigation system, I asked him this question—“What is the most important thing, and what is the key strategy for the state government, to reduce the number of medical accidents?” His answer was “HIT.” This surprised me because I did not anticipate such an answer. He explained that all data from accidents must be collected and ana-

(Slide 1)

The aim of Health Law in the U.S.

- **"access, quality and cost," this is the catchword, meaning law should encourage and support more access to medicine and better quality of medicine at reasonable cost.**
- **To accomplish these three ends, the most important and reliable key is DATA HEALTH or Health IT.**

1

(Slide 2)

Health Care IT The Essential Lawyer's Guide to Health Care Information Technology and the Law (2014 ABA)



2

(Slide 3)

EHR benefits

- 1) enhance care and reduce costs
- 2) improve overall efficiency and reliability of health records
- 3) interoperability and coordination
- 4) collection of data for epidemiology and clinical research
- 5) anonymous data used for resource management, quality improvement and public health
- 6) clinical real time access to patient data to support patient care
- 7) patients' participation made possible and meaningful
- 8) improve clinical trials and personalized medicine
- 9) increase transparency and reduce administrative costs
- 10) create the new jobs and innovation
- 11) support to reform of health care system

3

lyzed, and this surely convinced me.

## Aim of the Health Laws in the USA

I have taught about healthcare and the law at law schools and in other places, and I had some very good experiences in teaching with Dr. Yasushi Kodama, who is a lawyer and physician. He answers any questions I have about healthcare.

When I started reading casebooks on the US health law, every book I read says that lawyers involved in the health laws or healthcare should aim to manage “access,” “quality,” and “cost” (Slide 1). “Access” refers to better accessibility to healthcare, namely, how healthcare should be available for anyone—this is a major problem in America. Obamacare improved the situation to a certain extent, but with the backlash that is currently taking place, no one knows what will happen. Their system is very different from the universal health coverage in Japan.

The second point, “quality,” refers to better

quality of healthcare. “Whatever care that is available” is not good enough; healthcare delivery has to aim for better care. The last one, “cost,” naturally means that the cost to patients has to be reasonable and should be sustainable for society as a whole. Balancing, maintaining, and developing these three targets is what lawyers should aim to accomplish—this is what a law school textbook teaches first. This is very different from the health law education in Japan, which pessimistically talks about nothing but how to deal with medical malpractice lawsuits.

Ultimately, law education in the US concludes that the key concept in solving these three targets is “data health” or HIT, although much depends on the efforts of individual physicians. This conclusion, too, hit home to even someone like me who has poor skills in handling data and computers.

## Pros and Cons of the Digitized Health Data

Recently, I purchased a book titled “Health Care IT” (Arthur Peabody, Jr. 2014) published by the American Bar Association (ABA) (Slide 2). This book on IT put together by the ABA is very interesting, and is written in a way that an amateur in health IT, such as a lawyer like me who is not a physician, can understand.

It talks about many benefits of developing the Electronic Health Record (EHR) System (Slide 3). These benefits are similar to those listed in the MHLW’s Grand Design for Healthcare ICT in Ja-

pan in 2001, which Professor Yamamoto introduced in his keynote lecture, so the ideas are universal in that sense. In this Grand Design, quality improvement in healthcare and cost saving are at the top of the list. IT naturally comes into play when talking about cost and quality. Improved efficiency and reliable medical records—I believe these two are essential. You can't remember all the vaccinations you had, right? It would be a great help if there is a good record of such information somewhere.

So, information sharing and communication are important, and health data are very important for epidemiologic and clinical research; therefore, health data should be used—and should be available—to improve to healthcare management, quality improvement, and public health. The use of health data is not just for the public good; it is also for the benefit of individuals. With HIT, my medical history, including what kind of treatment I have undergone, what prescriptions I am taking, and what allergies I have, will be all available if I fall unconscious or must be carried to a hospital in an ambulance.

However, there is also a risk in using HIT (**Slide 4**). Listed at the top of the list was that people might resist this sort of technology. The first wave of resistance might come from healthcare institutions, which will be asked to bear the costs. It is understandable considering the initial cost incurred, and I believe some form of aid would be necessary—however, what is really behind their mind is the fear against advancing HIT. I would imagine that they have their reasons, but there is a clear sense of fear in general against advancing technology.

Let's talk more concretely here. Is it really possible that someone's private information, such as their history of medical or psychiatric care or sexually transmitted disease, will be exposed to the public? There may be cases in which the data are recorded incorrectly. Let's say, I have an allergy but the data were entered wrongly or tampered, and I was then given a prescription or underwent surgery. Such error in recorded data is a problem

(Slide 4)

#### EHR risks

- 1) Resistance to the use of technology
- 2) data breach and unauthorized use with invasion of privacy
- 3) data breach and error resulting in threats to the health of patients

that can have negative consequences.

So, is it better to not do anything for HIT? This is not a matter that should be simply decided by majority vote, but many people, including myself, believe that there are benefits to IT development and that things will move in that direction anyway. In short, there are many benefits to HIT development, and they are diverse. It can contribute to social development, and sooner or later each of us will benefit as well. However, there are two concerns that need to be alleviated: the invasion of privacy due to data breaches, and the threat to healthcare quality for individuals due to these data breaches.

### Revision of the Japanese Personal Information Protection Act

The revised Personal Information Protection Act of Japan will take effect on May 30 of this year. So, why was it revised? The Act was first legislated in 2004 and was then revised only a decade or so later, so what happened during these years is key. Normally, a law is not revised in such a short period.

Reportedly, the way that the Act addressed certain issues was insufficient—but I do not believe that it was necessarily the case. Nevertheless, the focus of the revision emphasized enhanced privacy protection. The beginning of the Act addresses effective use of personal information and the protection of personal information when considering its use. So, it first lists both the use of the data and their protection. It would have been better to re-ti-

the Act as the Personal Information Protection and Positive Use Act, but the original title said personal information protection only, so everyone thinks that it addresses nothing but protection—this is very unfortunate.

Now, there were two factors behind the revision, and one of them began in the EU. There are several Japanese laws whose creation was externally pressured, but candidly speaking, this pressure is normally from the US. I will skip the details for now, but this time, the EU established a set of global standards that define the minimum requirements for privacy protection. The 2004 Act already in place in Japan did not meet these EU standards, so the EU gave it an F-grade. I think that this is a type of interference in the domestic affairs, but there is nothing we can do. So, one reason that the Act was revised is to have it meet the EU standards so that the EU gives us a passing grade this time.

However, there was another reason for the revision, which was actually far more significant. In the first place, EU—Japan trading did not suffer from the “failed” Personal Information Protection Act of Japan, so Japan was not really in trouble. Still, conforming to the EU’s ideas is perhaps an admirable attitude.

The second point is the issue of “big data,” which is lately a hot topic and is what has brought us here today. Even the government is beginning to say that now is the time for “big data” use. The government decided to revise the Act to use “big data” better, not only in the healthcare sector but also in all areas of industry, as a way to innovation and economic revitalization.

### Revised Personal Information Protection Act: Actual facts

So, the Act was revised with the intention of making it easier to use health data and other personal data; however, actual result was not so, rather it became too protection oriented. The first change made in the revision was to expand the areas that are subject to law (**Slide 5**). The businesses that handled 5,000 or fewer cases of personal information were not subject to the old version of

#### New PIPA in fact

- 1) Scope of data protection enlarged
    - Entities with less than 5000 data are now covered.
  - 2) Establishment of the central agency of data protection
  - 3) Data subjects' right to demand disclosure and to consent made clear with direct enforcement.
  - 4) Individually Distinct Code is per se personal information which could include genetic information.
  - 5) Sensitive personal information includes health history data.
  - 6) Anonymization narrowly defined, making the creation of big data difficult
- These amendments are influencing badly against the more and better uses of health information.

5

the Act, and this did not meet EU standards. So, small businesses are also covered in the revised Act. In the healthcare sector, small clinics with fewer than 5,000 patients are now all subject to the Act.

Second, one reason that the Act did not meet the EU standards was the lack of a centralized responsible agency similar to the Data Protection Agency of the EU. Our practice was to appoint the main-handling ministries and agencies for different types of businesses to manage data protection—for example, the Ministry of Land, Infrastructure, Transport and Tourism for taxi companies, and the Ministry of Environment for environmental businesses. So, data protection was in place but separated. The EU did not think this was good enough, so they labeled Japan as negligent for not having a single centralized agency responsible for data protection. The Personal Information Protection Committee was thus created. Can they handle it all? Yes, in legal and formal terms, but practically speaking, I doubt it and it may be problematic at best.

The third change in the revision was to address the EU’s claim that the right to demand disclosure or correction of personal information did not seem to exist and that no one seems to be entitled to this right. This was simply a misunderstanding on the part of the EU. Filing a lawsuit against a breach of information or wrongly recorded data was always possible through the Civil Code. However, it is quite understandable how the EU could have misunderstood because this was probably not ex-

plained enough. Anyhow, the EU said that the rights of the patients and the individuals should be clearly stated, and so they are now.

The fourth change was to introduce the idea of a personal identification code to Japan, which in itself expanded the concept of personal information. Anything that has to do with this personal identification code is now subject to the regulations of the Act. This raised a major question as to what constitutes personally identifiable information in the context of genetic data. The currently available answer is that “not all genetic data are considered personal information,” which is quite ambiguous. So ambiguous that any research involving “personal” genetic data will need to have consent from the subjects in advance, which will make things extremely difficult for researchers. Anonymized or not, a study that includes genetic information may be difficult if the data in question are considered personal.

The fifth change was the introduction of the idea of “sensitive information.” In the old Act, there was only one kind of personal information. In the revised Act, however, a new category of “sensitive information” was created for particularly important personal information. Medical history was added to this category at the last minute when finishing the bill for the revised Act. A medical history is a history of medical and health records. Thus, all health information can be considered part of medical history, and therefore sensitive information. Health data are now so heavily protected that the “positive use” part has been neglected in some ways. This is really difficult to understand.

The sixth change was about making anonymized “big data” available for use; however, the requirements for the anonymization are so strict that any data that can be reverted back to identifiable information under certain conditions are not considered as anonymized. The use of health data requires that the data be traceable. Thus, health data have to undergo a process called “linkable anonymization,” which is somewhat old-fashioned, before being used. However, the revised Act utilizes so narrow interpretation that linkable anonymization

(Slide 6)

### Bad influences against health IT

- Many examples of fear and anxiety, among others:
  - 1) Genomics academics are feeling that their research is almost impossible, since genomic information may be classified as Personally Distinct Code.
  - 2) Since health history is now classified as sensitive information, The new PIPA becomes a tremendous barrier against collection of health data.
  - 3) The PIPA covering national hospital and universities has made a restraint for health research, a bit narrower than private universities.

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is not considered anonymization because the data can be reverted back to its original form. Maybe the Ministry of Internal Affairs and Communications was behind this—I really do not know.

### How and Why did This Happen?

So, in short, this revised Act will do nothing but clearly prevent the positive use of “big data” overall. What happened to the basic policy of revising the law for positive data use? How did this happen? I am only an outsider, so I really do not know. The Japanese government is not monolithic; each department is thinking differently. So, I speculate that a hard-working ministry in charge of protecting personal information thought nothing but of meeting the EU standards to serve its own interests. They were not interested in the other key purpose of revising the Act, which was to help use “big data” better.

In some cases, the grounds for protection are uncertain, and information is protected simply just because protection must be in place. In the case of healthcare, privacy is surely protected, but people might die as a result. This is like putting the cart before the horse—it is foolish.

### Revised Personal Information Protection Act: Negative effects

Now that the revised Personal Information Protection Act is in effect, some negative influences are expected to take place (Slide 6). First, genetics researchers will no longer be able to use any genetic data because they are considered to be per-

sonal identification codes. I am already hearing such a pressing claim from some academic experts. At this rate, I also fear that genomic research will no longer be possible in Japan.

Second, now that medical history is considered sensitive information, it will be extremely difficult to obtain health data, which could be a serious threat to research projects such as new drug development.

Japan is a crowning example of the Galapagos phenomenon when it comes to privacy protection. In addition to the Personal Information Protection Act, different municipalities are legislating similar laws and ordinances. As a result, there are now close to 1,000 personal information protection laws and ordinances in Japan. Personally, I have never heard of anything like this in other countries, but maybe there are instances somewhere in the world. Nevertheless, this situation is clearly rare, and I do not know how we have arrived at this strange situation.

So, what is the result? Now, there are three national laws for privacy protection in Japan—one targeting the government administrative agencies that govern national hospitals; one targeting independent administrative corporations, which were formerly the national university hospitals; and one targeting private institutions, clinics and hospitals. There are some notable differences even among these three acts. Academic study is excluded from the scope of the law per se in the private area, which means that academic use of personal information is allowed in principle. In the area of national university hospitals, in contrast, the Act says academic use of personal information is permitted but except when these studies involve certain risks. So, this exception clause has become a source of concern. The law even states that no academic study that may damage the interests of individuals is allowed. It is not understandable that academic researchers in private university hospitals and those in national university hospitals are subject to different laws and treatments.

In reality, ethical guidelines for medical research never exclude academic research in their

scopes, and privacy protection has always been strictly regulated in every sphere, private and public. These guidelines remain, but now the Personal Information Protection Act could come into play as a factor impeding research more directly. Health researchers and many others are concerned for the future development of healthcare.

So, the Japanese legal system for personal information protection is flooded by nearly 1,000 laws and ordinances, which is a very strange phenomenon—but it would not really matter if their content is all the same. Typically, laws are copied, anyway—but, these laws ordinances are not all copies. I asked someone to check if academic study is exempted from the personal information protection ordinances, and it turns out that about 30% of prefectural ordinances and over 60% of municipal ordinances do not have such clearly stated exemption clauses. A city hospital, city college, or prefectural university in these areas will be subject to the city and prefectural ordinances, and therefore, their academic study will be legally impeded as well.

## **Enactment of the Health Infrastructure for Next Generation Act**

Now that this sort of legal system has been established, a different department in the government came up with a plan for a breakthrough to solve this situation. Only a law, not guidelines, can act against another law, after all. A breakthrough law—commonly called the Health Infrastructure for Next Generation Act, which I have personally named the “landmark act”—was passed by the National Diet on April 28. Unfortunately, hardly any media organizations, except the Mainichi, reported on it. Still, this act clearly states that health data can be legally used for research and development involving healthcare, despite the Personal Information Protection Act (**Slide 7**).

So, what does this mean for the future? The most basic framework is very simple. Patient data from each hospital will be collected to create “big data.” Now, what is important here is not what happens to a patient named Higuchi, but what hap-

(Slide 7)

How we should respond to the new PIPA from coming June

- **Act versus Act**
- On April 28, 2017, our Parliament passed a new landmark Act, Health Infrastructure for Next Generation Act (HINGA).
- To make use of health information available for health research and innovation, Government certified entity anonymize the health data to distribute anonymized health data for research and innovation.

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(Slide 8)

What we should do further?

- 1) Research done by researchers of national hospitals and national universities should be more clearly exempt from PIPA.
- 2) The sharing of health information for the benefit of patients when medical treatment needed should be clearly made exempt from PIPA.

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(Slide 9)

What we should do from now on

- 3) The sharing of health information for the purpose of health research and public health should be generously possible.
- 4) Finally, Make guidelines on medical ethics for health research sponsored by Japan Medical Association(JMA) to show that health professionals are capable of professional autonomy. Also the training program should be established under these guidelines by JMA which should be a model for other countries.

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pens to patients who have the same disease that I do. So, the data will be anonymized but tracked, which means that the data will reveal information such as how many years I have lived and which drugs worked very well. To enable such tracking, several Authorized De-identifying Organizations will be created, and the data they anonymize will be made available to various projects. This way, security is ensured and due consideration is paid for the use of the data under the new law.

### What Should be Done Further ?

Now, can this Health Infrastructure for Next Generation Act solve everything? Someone told me differently, and I will list four concerns (Slide 8).

The Personal Information Protection Act tends to apply more strictly to independent administrative organizations that were once national universities or national university hospitals, so they should be assured that the Personal Information

Protection Act is not their concern. Of course, a decent procedure is a must. Solid security measures must also be in place because it is only natural to care for security and privacy. However, it should be made clear that, unlike the Personal Information Protection Act, the Health Infrastructure for Next Generation Act will not make the use of health data for health research difficult. This point has not been made clear in the current Health Infrastructure for Next Generation Act.

Second, it is only reasonable to share information for the benefit of patients. Privacy protection should not be without due cause, so it should be clearly stated that the use of health data for health research is not subject to the Personal Information Protection Act.

Third, health data is not only meant to serve individuals; they are public information and are therefore meant to serve the good of the public (Slide 9). For example, I have been suffering from a disease for about 40 years now, but my physician is determining what treatment is appropriate for me based on the data of other people with the same disease, as well as his own knowledge and experience. If I am allowed to claim and declare that my health information not to be used for others, it would be nonsense in the first place. That's being a free rider.

Of course, privacy and security are important and essential as premises, but permitting a person not to use his/her data for public health just because the data belongs to that person is a misplacement of the information control right. It is not the

exercise of a right; rather, it is purely the abuse of that right. Permitting such a right is ludicrous in the first place, and it should be made clear that the sharing of health data for health research or public health is allowed.

Finally, there will be many risks and ethical issues involved in the use of health data. Furthermore, new questions and problems will emerge one after another as technology advances. It is not possible to always cope with them through law, as it takes time to create a law. This Health Infrastructure for Next Generation Act was indeed an exception. I believe it was a case that the health-care community was alarmed by the Personal Information Protection Act so much that the government moved quickly. The health data issue, including the risk management and ethical challenges involved, will require further efforts by the

government; however, I believe that the Japan Medical Association (JMA) should be taking an initiative in setting up guidelines.

Training on health data issues should also be included in the core curriculum of the JMA Continuing Medical Education Program. Many people will still be lost even when guidelines are available somewhere, and they need to undergo a certain training program as a prerequisite. Today's conference is hosted by the JMA, so I would like to take this opportunity, and be candid in saying that it will be essential to the true practice of professional autonomy. Maybe no other national medical association has reached out that far, but today, I would like to propose that Japan could become a model case.

Thank you for your attention.

● Comment ●

## Health Database: Are we ready to step forward?

Dong-Chun Shin  
Professor, Yonsei University College of Medicine



I have been engaged in WMA activities for over 10 years. We always thank JMA and Dr. Yokokura for his continuous leadership and contribution to the WMA and congratulate again Dr. Yokokura to be President-Elect of WMA. We expect more leadership from Japan and Asian region in the global arena in various kinds of health issues including health database.

My title is “Are we ready to step forward?” I think we are ready to go. Before going on my talk, I will try to briefly summarize the previous four prominent speakers’ talk.

Firstly, Professor Yamamoto and Professor Higuchi mentioned that Japan has two acts, which can be contradictory; One act will promote and the other act will discourage. But I think these two tracks should and can be complementary, not contradictory. We can start to step forward on the basis of security measures, some kind of legislation and protection law. Japan is ready by the amendment of PIPA, and I hope you can minimize the risk of health database utilization down to the virtually zero level of risk by that legislation.

We are talking about virtually zero risk in risk science and risk analysis domain, in academic domain. I have been engaged in that area for my lifetime. So we should talk about what should be the virtually zero. In modern society, we cannot live without any risk, from disaster, from technology development, from environment or from IT. We should be prepared to live in this risk society.

People say that before the 21st century we could

not live without much knowledge of economy. That is still effective. But in the 21st century, some people say we are living in risk society, so we have to be prepared to be risk literate. The society can be divided by risk literate society and risk illiterate society. We have to educate and train what the risk is and what risk means. We also have to communicate among stakeholders such as the general public, patients, healthcare providers, legislators and policymakers, to talk about what is the virtually zero risk.

If we have well-designed policies and regulations to make this kind of database utilization possible, we are in the track with very little virtual risk. However, those kinds of guidelines and legislation are not enough to make virtually risk zero status. We need to continually talk about the cases in some country and bridge it to other regions with efficient communication. We continually share our experiences to protect the infringement of patients’ safety.

Japan has a good cohort for Japan sentinel project, which is an information project and also the Tohoku community, a very desirable third generation cohort. That kind of cohort is expected to produce unbiased finding of disease etiology rather than hospital data.

Dr. Robert Wah also mentioned that research on database health information has started from electronic medical record (EMR) and then is moving to the community cohort study, two kinds of million people cohorts. He also told us lots of import-

ant information to take care of patients and take care of prevention especially. Dr. Wah also mentioned promises and pitfalls, and WMA declarations in the aspect of security issues. He showed us a way in the future in the aspect of data security and better use of data for better healthcare. We were entertained by several very nice Qs & As after his presentation. Some participant here asked if that kind of system is feasible in the future or not. We have to think about technology across society. We have much bigger pictures to deal with these very important issues. These kinds of same questions will be applied to any situations in our risky society; How can we make people safe, how can we make people in the state of peace of mind. I can tell in Japanese language that “anshin” equals “anzen” plus “shinrai”. So “anzen” is technology. We try to make technology perfect to ensure patients safety for their personal information. But that is not enough. If people do not believe technology, if people do not believe policymakers, government or experts, it does not work. So trust is another hand or another leg to go. We have two legs. One is anzen or security, and the other one is shinrai. It can make peace of mind, anshin, together. This equation is very common in the risk analysis society and the answer from Robert Wah is something similar to this concept. So I agree with his opinion. We need to make a consensus among stakeholders. Continual communication and risk communication are required.

Dr. Ju Han Kim gave us quite an interesting presentation using his own genome data. Some medical doctors in history tried some vaccines to himself and looked what was going on, and showed us clear logic why this kind of work is critical to take care of patient, individual patient and save the social cost from drug misuse. Drug misuse could be assessed more precisely and reduced with genomic data or health database. The pharmacovigilance project is also impressive, and I want his project to keep growing and expect many avatars in Korea. But still, security issues are left, because of cellular phones. A one-to-one, patient-doctor relationship does not make a big problem. But the mobile

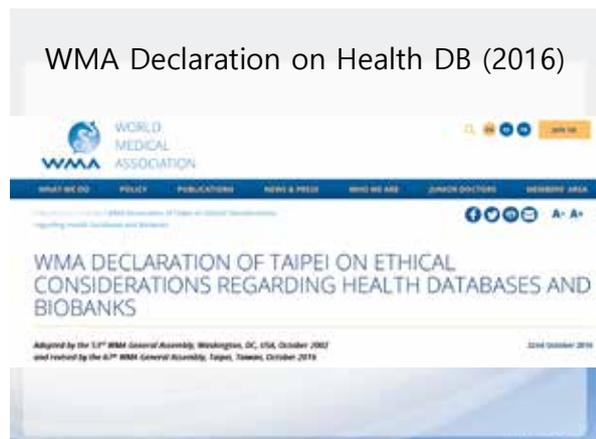
information can be hacked or leaked in some way. I think it is a big issue in his work.

Dr. Chen introduced us to Taiwan’s system from past to present and to some future prospects, and showed us how much we can save on paper and so on, by applying this kind of information system. It makes me happy because I am a supporter of making hospitals green. Energy saving and material saving in hospitals are very important because we are living with cost-containment in healthcare sector and we have to concern about the cost reduction in our healthcare industry. So green hospital is my recent work. Also he mentioned a very nice community project in a greater Puli area in the middle of Taiwan, in which almost 90 percent of patients are covered, so it is a perfect cohort from which we can expect many good results. In the future Taiwan will introduce partly the capitation system, so it will make a big change for the behaviors both of patients and of healthcare providers and I hope this change will ultimately enhance the value of patient care and the health of the people.

Professor Higuchi gave a very nice, comprehensive talk, and introduced some basic concepts and principles, and also presented problems in Japan. He mentioned about a medical doctor in Wisconsin. Dr. Murray Katcher tells us that the key to improving patients’ safety and prevention of medical accidents is health information technology. I agree with that. As an individual medical doctor, we accumulate patient care experiences in our lifelong career. There is an individual doctor’s embedded information, and all this kind of information is shared by health information technology, and enormous number of medical doctors’ lifetime information is embedded in one small IT. It is great. As you know we are already in the era of fourth industrial revolution. Artificial Intelligence system or AI can take part in our medical work in the near future. In that case, this kind of accumulated information in some system makes us happy, or no? It will depend on our decision and our way of thinking and working.

According to Prof. Higuchi, access, quality and cost are the key aims of health law in the U.S., and

(Slide 1)

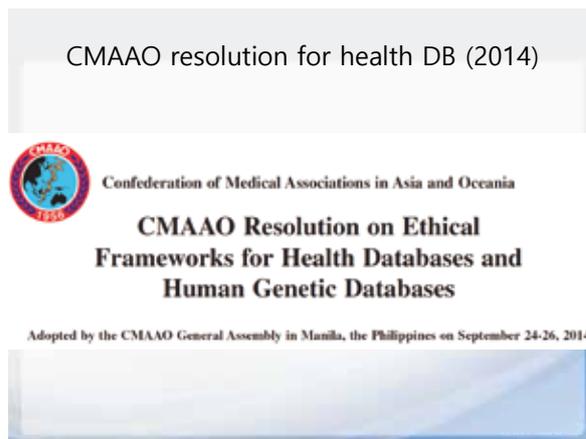


to accomplish these three ends, health IT is the important key. He also introduced some points written in the book titled “Health Care IT” and in addition to all the benefits we already talked about, there are job creation, transparency and healthcare reform as EHR benefits, through reengineering of precisions in healthcare sector. We need IT application in healthcare sector and we do need to minimize the risk of this new way of work down to virtual zero. In order to be in that state, in that step, we have to discuss more among medical people, legislative people, general public and patients.

Prof. Higuchi also mentioned that PIPA in Japan amendment will be effective this month to strengthen the protection of information. But as I told you, I think this is a basic step to go forward although he talked us many negative effects. It is a legislation, much stronger than guidelines or framework, but these legislation can be complemented by other legislation like the next generation information legislation. This level of strict guideline might be achieved by new technology. If new technology is growing, we can make everything individual, every record permanent and every information easy, and then we can make, and almost fulfil that kind of strict legislation in our future society.

Let me stress once more the consensus among stakeholders. Who will drive or initiate this whole work? In Prof. Higuchi’s last slide, JMA, medical association, medical people, have to be prepared with very high standard of ethics. Ethical standard is needed to initiate this work. I think medical doc-

(Slide 2)



tors are well educated, well trained to take care of patients and people, to make people healthy. Their ethical standard can be going up even higher to lead the society, to make all these things possible, to make medical information usable and applicable, and to make efficient communication to people in the other sectors, patients and the general public. That is my summary.

I already spent, almost used up my time, but these are my slides I prepared in advance. WMA Declaration of Taipei is already mentioned (**Slide 1**). We have CMAAO, Confederation of Medical Associations in Asia and Oceania, and adopted a very nice resolution in 2014 (**Slide 2**). I am Council Chair of CMAAO group and JMA serves as the Secretariat and holds Secretary General for a long time. In this resolution, we have three recommendations; “Each NMA (National Medical Association) shall urge each government to prepare the necessary legal systems and procedures”. “Each NMA shall exert efforts in the development and distribution of education and training programs”. It is very important. Also, “Each NMA shall exert efforts to support research activities on ethical approaches”. - again it is very important to raise young medical doctors in this way- and “to monitor whether such ethical principles are being well followed”.

In Korea, it is very similar to Japan, but in Korea the benefit is that data is stored in one system. It is very powerful. But we cannot use that without any permission from the government (**Slide 3**). Government sometimes permits us to use it in the case of social benefit or patient benefit. But it is

(Slide 3)

### Personal Information Protection Act, 2011 in Korea

• **Article 1 (Purpose)**

– The purpose of this Act is to prescribe matters concerning the management of personal information in order to protect the rights and interests of all citizens and further realize the dignity and value of each individual by protecting personal privacy, etc. from collection, leakage, misuse and abuse of individual information.

(Slide 5)

### Future prospect

- The 4<sup>th</sup> industrial revolution (Industry 4.0)
- Precision medicine initiative
- Health DB Market and Commercialization
- Reward and right for own health information

(Slide 7)



not easy and is almost blocked. When you use it, we have data with anonymous type (Slide 4).

For future prospect, we are already in the fourth industrial revolution and precision medicine initiative (Slide 5). We have to be very cautious about commercialization of health information and reward and right for own information. Reward can be the medical science. Medical treatment en-

(Slide 4)

### Personal Information Protection Act, 2011

- Data exportation was strictly limited in order to prevent leakage of personal information
- Data coding: resident ID number → randomized secret code
- New randomized number should be given during clinical trials
- The same principle applies genetic research
  - Bioethics and Safety Act, revised 2013
  - Institutional Review Board

(Slide 6)

### Risk Governance

- Safety and Security of health DB
- Privacy and Misuse of health DB
- Transparency and Accountability
- Basic System for Risk Governance
  - ✓ National Medical Association Level
  - ✓ National Level
  - ✓ International Level

hancement is one of the great rewards to the individual patient. I will tell you about risk governance; safety and security, privacy and misuse of health database, and transparency and accountability (Slide 6). It is very important because it can make people trust us, trust the policy, so we need communication with transparent way, and accountable standpoint. We need to make basic system, which I think is now ongoing, at national and international level.

Lastly in general IT environment, in what is called IT governance, we assess IT maturity and we measure IT performance within the organization framework, strategic framework, operating framework and control framework (Slide 7). So, we pursue IT value in the core to improve the medical science and patient safety, by improving compliances, risks and security issues, to make this IT health database sustainable in the future.

Thank you very much.





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