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JAPAN MEDICAL ASSOCIATION

JMAJ

Recent Activities of the World Medical Association about Health Databases[*1]

—Development of the Draft of the Policy Statement and Future Revision Process—

Masami ISHII[1]

I will talk about the activities of the World Medical Association (WMA) to develop its proposed declaration on ethical considerations regarding health databases and bio-banks.

The WMA agreed to support the Icelandic Medical Association in its fight against an Icelandic Government bill to establish a central health database for the entire population of Iceland in around 1998. The WMA General Assembly agreed to a request that the WMA Secretary General should assist the Icelandic Medical Association in seeking to clarify with the Icelandic Government the incalculable ethical consequences of the data collection Bill.

The WMA General Assembly in Ottawa in 1998 expressed its position to support Icelandic doctors' strong will to fight against the Bill. The second slide cites the words of Dr. Torben Pedersen, then President of the Danish Medical Association who is supportive of the Icelandic Medical Association's efforts (**Slides 1 and 2**).

Its Council Session in Santiago in 1999 also confirms its commitment to patient confidentiality which is one of the most important cores about this problem (**Slide 4**).

The WMA and WHO held a joint seminar in Geneva in May 2000 entitled "Ethical implications of centralized health databases." A joint seminar facilitates both the exchange of information and the future development of policy by the respective organizations (**Slide 5**).

The WMA Council Session in Divonne-les-Bains, France in May 2000 decided on the need for guidelines after holding a joint seminar in Geneva with the World Health Organization, where physicians' representatives from across the world expressed their concern about the threat to privacy of patients' records. Dr. Anders Milton, the then Chair of WMA pointed that it is essential that to allay public concern about the growing development of these databases, internationally acceptable guidelines are drawn up to govern their use. And any guidelines must address the issues of privacy, consent, individual access and accountability (**Slides 6 and 7**).

The WMA General Assembly in Washington 2002 adopted a statement on ethical considerations regarding health databases. The first revision was discussed in the Council Session in Plague in 2012 with the Icelandic Medical Association as a rapporteur. This action was succeeded in Bangkok in the same year where a working group was established to develop a proposed revision of this document (**Slides 8 and 9**).

In 2013, the WMA General Assembly in Fortaleza, Dr. Snædal noted that there were several options for defining the scope of the WMA work in this area. The WG Chair made a motion requesting that the WG be instructed to continue its work on the broad concept of health databases. The motion was approved (**Slide 10**).

This year three doctors from the US, Korea and Iceland were invited by the Japan Medical Association to its conference on medical infor-

mation technology on February 9 and delivered a presentation, "Big Data/Analytics and the US Healthcare System: Big Opportunity, Big Responsibility" by Dr. Robert Wah from the AMA, "ICT and Healthcare in Korea, Present and Perspectives" by Dr. Dong Chun Shin from Korea and "Centralized Health Databases Lessons from Iceland" by Dr. Jon Snædal from Iceland (**Slide 11**).

The WMA also held a WG meeting in Reykjavik in March 2014 to more closely discuss this topic (**Slide 12**).

These efforts will be succeeded to the WMA Council Session which will be held in Tokyo in April of this year. We will expect further development of the discussion there toward the adoption of this document in its general assembly in Durban in the coming October (**Slide 13**).

WORLD MEDICAL ASSOCIATION

Proposed Declaration on Ethical Considerations

Regarding Health Databases and Biobanks

--Development of the draft and future revision process--

Japan Medical Association Auditorium
February 8, 2014

Masami Ishii, MD
Vice-Chair of the World Medical Association
Secretary General of CMAAO

Slide 1

WMA General Assembly, Ottawa Oct. 1998

WMA to support Icelandic Doctors on Fight against Bill.

- The World Medical Association has agreed to support the Icelandic Medical Association in its fight against an Icelandic Government bill to establish a central health database for the entire population of Iceland.

- The General Assembly agreed to a request that the WMA Secretary General should assist the Icelandic Medical Association in seeking to clarify with the Icelandic Government the incalculable ethical consequences of the data collection Bill.

Slide 2

WMA General Assembly (Ottawa) Oct. 1998

WMA to support Icelandic Doctors on Fight against Bill

Dr. Torben Pedersen, President of the Danish Medical Association, told,

- The proposed data on patient information would be financed and organized by a private licensee, possibly a pharmaceutical company, in return for which the licensee would have a monopoly on the data for research purposes.

- The database would contain all accessible information on patients from the Icelandic health system over the past two or three decades.

- He said the ethical risks of this proposal included other researchers being denied access to the data, the possibility of carrying out a complete DNA registration of the entire Icelandic population and the risk of individual patient information being identifiable, thus stigmatizing families and isolated population groups.

Slide 3

WMA Council Session (Santiago)   April, 1999

WMA Confirms Its Commitment To Patient Confidentiality

- Having heard representations from both the Icelandic Government and the Icelandic Medical Association about the creation of a national health database in Iceland, the World Medical Association has reaffirmed its commitment to patient confidentiality, the principle of informed consent and the freedom of scientific research.

- The WMA stands fully behind the position taken by the Icelandic Medical Association in opposing the Icelandic Healthcare Database legislation recently passed by the Icelandic Parliament.

- The WMA especially points to the need to protect the integrity of patient data and to have open access to all scientific data.
  The WMA urges all national medical associations and governments to ensure that science is furthered by continued research that in no way breaches medical ethics and patient confidentiality.

Slide 4

Joint seminar of WMA and WHO   May 2000

"Ethical Implications of Centralized Health Databases"

May 3, 2000
WHO Headquarters, Geneva, Switzerland

- This event has now been planned in conjunction with the World Health Organization.
- Other international organizations should be consulted to obtain their views on the ethical implications of Central Health Databases.
- A joint seminar should facilitate both the exchange of information and the future development of policy by the respective organizations.

Slide 5

WMA Council Session（Divonne Leis Van） May, 2000

WMA to Draw Up Health Database Guidelines

New international ethical guidelines for the development of centralized health databases are to be drawn up by the World Medical Association.

The association decided on the need for guidelines after holding a joint seminar in Geneva with the World Health Organization, where physicians' representatives from across the world expressed their concern about the threat to privacy of patients' records.

Slide 6

WMA Council Session（Divonne Leis Van） May, 2000

Dr. Anders Milton, Chair of the WMA
- It is essential that to allay public concern about the growing development of these databases, internationally acceptable guidelines are drawn up to govern their use.
- The public is rightly concerned about whether their right to privacy and confidentiality is threatened by these databases and whether information about them as individuals could be misused.
- Centralized health databases can make a tremendous contribution to the improvement of health.
- But the public's right to privacy and consent are essential to the trust and integrity of the patient/physician relationship and we must ensure that these rights are properly protected.
- Any guidelines must address the issues of privacy, consent, individual access and accountability.

Slide 7

WMA General Assembly (Washington), October 2002

Adoption of the WMA Statement on Ethical Considerations regarding Health Databases
- The privacy of a patient's personal health information is secured by the physician's duty of confidentiality.
- Confidentiality is at the heart of medical practice and is essential for maintaining trust and integrity in the patient-physician relationship.
- The primary purpose of collecting personal health information is the provision of care to the patient.
- Care must be taken to ensure that secondary uses of information do not inhibit patients from confiding information for their own health care needs, exploit their vulnerability or inappropriately borrow on the trust that patients invest in their physicians.
- Patients' consent is needed if the inclusion of their information on a database involves disclosure to a third party.
- National medical associations should co-operate with the relevant health authorities, ethical authorities and personal data authorities, at national and other appropriate administrative levels, to formulate health information policies based on the principles in this document.

Slide 8

WMA Council Session (Plaque), April 2012

WMA Statement on Ethical Considerations regarding Health Databases
- As a classification of 2002 policies, this document was considered during the 191st Council session in Prague, April 2012 to put this document on "major revision".
- The Icelandic Medical Association has been appointed as a Rapporteur.
- This document was circulated to NMAs for comment.

WMA General Assembly, Bangkok, 2012

  Dr. J Snaedal presented the proposed Revision of the WMA Declaration on Ethical Considerations regarding Health Databases and Comments, and proposed that a working group be established to further discuss the document.
  The Council set up a working group to look at the proposed Revision of the WMA Declaration on Ethical Considerations regarding Health Databases and Comments.
  The constituent members of the WG: Iceland, Denmark, US, Israel, Australia and Germany.

Slide 9

WMA Bali Council Session on April 2013
WMA Statement on Ethical Considerations regarding Health Databases

- Dr. Snaedal, chair of the working group, reported on the activities of the working group.
- Dr. Snaedal indicated that the draft pape presented to the Committee was not the final proposal for consideration, but only for information, reflecting the advancement of the discussion.
- That the proposed WMA Declaration on ethical considerations regarding health databases be referred to the Medical Ethics Committee for further consideration.

WMA General Assembly in Fortaleza October 2013
Proposed WMA Statement on Ethical Considerations regarding Health Databases

- Oral report by Dr. Snaedal, Chair of the WG
- Dr. Snaedal noted that there were several options for defining the scope of the WMA work in this area.
- The WG Chair made a motion requesting that the WG be instructed to continue its work on the broad concept of health databases. The motion was approved.

Slide 10

JMA Conference on Medical Information Technology

Feb. 9th, 2014

JMA Auditorium

International Session

- "Centralized Health Databases Lessons from Iceland"

  Jon Snaedal, Chair of Medical Ethics Committee of the Icelandic Medical Association
  Former President of the World Medical Association

- "ICT and Healthcare in Korea, Present and Perspectives"

  Dong Chun Shin, Professor, Dept. of Preventive Medicine Yonsei University College
  of Medicine Administrative,
  Director, Yonsei University Severance Hospital,
  Chair, Executive Committee of International Relations, Korean
  Medical Association

- "Big Data/Analytics and the US Healthcare System: Big Opportunity, Big
  Responsibility"

  Robert Wah, President-elect of the American Medical Association

Slide 11

**WMA Work Group meeting on Health Databases and Biobanks
Reykjavik 7. March 2014**

Agenda – final draft

09:00 - 09:15 Opening of the morning session

Jon Snaedal, Icelandic Medical Association (IcMA)

09:15 - 09:45 "IT technology in the Medical Service"

Robert Wah, American Medical Association (AMA)

09:45 - 10:15 "Big data, research and ethics"

Mads Koch Hansen, Danish Medical Association (DMA)

10:15 – 10:45 "Use of Health Data in a University Hospital"

Maria Heimisdottir, IcMA

11:00 - 11:30 "Consent in health care and data protection law - Possible impacts of the EU's
(Draft) Data Protection Regulation on consent in research"

Annabel Seebom, WMA

11:30 - 12:00 "Biobanks, practical use in a divergent society"

Ames Dhai, South African Medical Association (SAMA)

12:00 - 12:30 "Ethical aspects of Biobanks"

Vilhjálmur Árnason, IcMA

Afternoon. Closed session of the WG.

Slide 12

WMA Council Session (Tokyo), April 2014

24–26 April 2014

Hotel Nikko Tokyo

- Thursday, 24 April
  Opening Plenary Session of the Council
  Medical Ethics Committee
  Finance and Planning Committee

- Friday, 25 April
  Finance and Planning Committee
  Socio–Medical Affairs Committee

- Saturday, 26 April
  Council Plenary Session
  Conclusion of Council Session

Slide 13

The Medical Doctor Qualification Certificate Project by the Japan Medical Association[*1]

Kazuhiro YANO[1]

The development in information technology (IT) is rapidly advancing in Japan, and its impact is felt in the healthcare and welfare sectors as well. Efforts have been undertaken to enhance care practices by taking advantage of IT through sharing and analyzing healthcare information.

However, the hasty introduction of IT has raised concerns with respect to security and privacy protection. Further, cases of identity fraud, where unscrupulous individuals pretend to be physicians, have become a social problem, raising concern regarding a basic credential system for medical practitioners.

In response to these circumstances, the Japan Medical Association (JMA) has been continuously making efforts in developing a safe and secure environment for healthcare and welfare by striving to understand the "bright and dark sides" of IT, given its mandate as an organization that represents physicians in Japan.

As part of our efforts, we offer the service of the JMA Certification Authority (JMA-CA). It is tasked with verifying the status of national medical license holders, which is the most basic foundation in this field. This service, which is interconnected with the Ministry of Health, Labour and Welfare's system, enables electronic verification of the license status of physicians (**Slide 1**).

In addition, the JMA Electronic Certification Center (JMA-ECC) was launched in May 2013 as an affiliated internal organization to manage the JMA-CA. The JMA-ECC issues smart cards called Medical Doctor Qualification Certificate upon strict review of the license status and eligibility of physicians. The JMA-ECC also offers support services for the preparation of a safe and secure IT infrastructure for healthcare information using the Medical Doctor Qualification Certificate cards (**Slide 2**).

There are two ways to use the smart card: one is in adding an electronic signature to a document; and the other is in authenticating one's identity when logging in the network system (log-in authentication).

As the name suggests, an electronic signature, or e-signature, enables the cardholder to sign an electronic document electronically. Adding an e-signature to a document in the healthcare network system helps prove the authorship of the signed document as well as the active license status of the author as a physician. If the content of an e-signed document has been altered, the electronic properties of the document will allow others to detect the changes. This function is

Slide 1

Slide 2

Slide 3

Slide 4

Slide 5

crucial in medical practice because such altera-tions—changes in prescription information when a physician is notifying patient information to others, for example—could result in the dif-ference between life and death for patients. An e-signature can prevent such an incident.

Another function, identity authentication, is used when sharing patient information through IT to verity the eligibility and qualification of the person accessing the system. If a non-eligible person can access patient information, the duty of confidentiality among physicians may be com-promised. This function is offered as a secure means to verify the credibility of physicians' license. The general image of the smart card is shown in **Slide 3**, and examples of its use are shown in **Slides 4 and 5**.

An example of an e-signature is shown in

Slide 4, which describes the steps involved when adding an e-signature to a letter of referral pre-pared using a PC. In Japan, the custom is to use a name stamp instead of a signature, and as such, the image here on the sample electronic letter of referral also uses the image of a stamp. The e-signature (e-stamp) serves as a guarantee that a physician wrote the letter, and that the document has not been tampered with after the e-signature was added.

In the example shown in **Slide 5**, the network system verifies the license status of the user (i.e., a physician) when he/she accesses healthcare information (patient information) through IT. As shown here, the Medical Doctor Qualifica-tion Certificate cards issued by the JMA-ECC are used as secure proof of identification as phy-sicians within the IT realm.
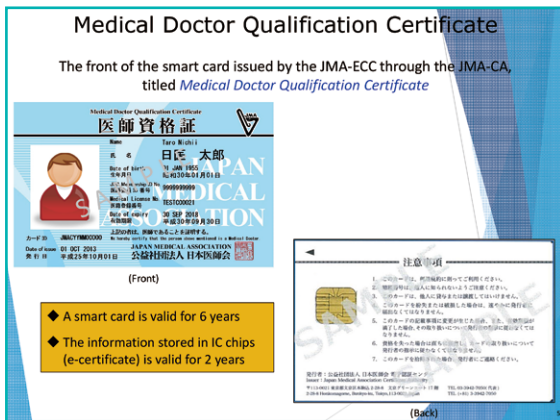
Slide 6

The next slide (**Slide 6**) shows the front and back of a Medical Doctor Qualification Certificate card.

The front bears the name of the card, *Medical Doctor Qualification Certificate*, and lists the cardholder's information, such as the full name, date of birth, and physician registration number. Therefore, through this card, the cardholder can prove his/her license as a physician not only in the world of IT but also in daily life by physically presenting the card to others.

At present, the card is not accepted as an official proof of identification because it is regarded as simply a certificate issued by the JMA. However, we are negotiating with various other parties and working toward its acceptance as an official proof of identification for physicians.

Through these efforts, the JMA will continue to promote and propagate the Medical Doctor Qualification Certificate cards in both the IT world and daily practice by offering secure credentials for physicians. By providing this viable identification system, we hope to help build a safe and secure healthcare provision system in Japan that would protect patients and the Japanese people at large.

Centralized Health Databases: Lessons from Iceland[*1]

JMAJ 57(2): 68-74, 2014

Jon SNÆDAL[1]

[Slide 2] The Iceland is exactly the size of the State of Ohio in the United States. 102,000 km^2 to be compared with around 380,000 km^2 of Japan. As you can see, the population is dispersed along the coast because the inlands are mostly highlands and glaciers. We also have volcanic eruptions every 5 years on average, some of them are small, but others are of international proportions. I would like to give you some figures in the demography and history of the country, which are relevant to these issues.

[Slide 3] The population is small as you can see; 320,000 individuals, and 8% are foreigners. It was one of the last countries in the world to be inhabited by humans. First colonists arrived around the year 850, and there were no inhabitation of any kind before that time. The origin of the colonists was believed to be mostly Norwegian, but it was later confirmed by DNA testing that they came both from Norway and the British Iles. Some of them were married and already brought their wives with them, and others who

Slide 1

Slide 2

Slide 3

Slide 4

Slide 5

Slide 6

Slide 7

were single captured females from Norway and the British Iles and brought them to Iceland.

[Slide 4] The history of the country, as you can see, is short. It was inhibited during the times of 870 to 930. The populations around the Year 1000 was 60,000. Since then, there were many difficult times for centuries, and I would like to dig a little deeper on that.

We have evidence of natural catastrophes and epidemics on several occasions for centuries, and the population was diminished by 25-30% each time. So, the population at around 1800 had not increased a bit since the original inhabitation. This created what is scientifically known as a founder effect. [Slide 5] When a population of humans or other animals is hit by a catastrophe, the population size diminishes significantly. When it happens repeatedly, the population experiences a founder effect, making the population more

homogeneous that it originally had been.

[Slide 6] This is the basis of the idea of the *centralized health database* (hereinafter referred to as the CHD)—to use the exceptional constellations of the population in research, and to use the homogeneity formed by the founder effect that is very specific in this country. The basis for this was the existing database inside a private company called the deCode Genetics, which still exists as one of the biggest genetics research facility into the world.

[Slide 7] Inside the company, they established 3 distinct databases, which I will describe further. These databases can be linked—technically. However, they are under strict supervision by the data commission. The situation inside the company has not created any problems because they have been working with the Ethical and Technical Commission, and later with the Data

The Genealogical Database

"Book of Icelanders"

The database is now in the public domain, everyone has access

It contains personal information on 830,000 persons that have lived in the country since the settlement

The data is almost complete 100 years back (96%)

The data is quite accurate 200 years back

The data is fairly accurate 300 years back, since the first census in 1703

Slide 8

Genetic Database

A Database containing genetic information of individuals from several seperate projects inside DeCode Genetics (ca 100,000 samples) in collaboration with clinical scientists

These projects are not linked within the database without an explicit consent:
- by those patients that had allowed for extended use <u>and</u>
- by the Data commission

Slide 9

Protection Commission and the Science Ethics Commission. So there were no problem in this regard, and many research facilities and companies follow the same procedure more or less.

I will now describe specific databases in more details. **[Slide 8]** The genealogical database contains not only all living individuals in the country, but also the information dating 1,000 years back that we have access to. We have almost complete population data for the 20th Century. The data are quite good 200 years back, and fairly good 300 years back since our first nation-wide census conducted in 1703. This population data book is called the *Book of the Icelanders* and is open to the public; you can create an account and see to whom you are related. However, you are only able to look up from your own perspectives. You cannot look up 2 separate individuals to see if they are related; so you can never be a third-party. One novelty that came out of this is a software application for mobile phones, which became very popular among young people as a small entertainment in the evening hours to see who you are related to. Although it was not the initially intended use of the data, the application became very popular. So, this database became very popular in research, both inside and outside the deCode Genetics.

[Slide 9] The next database is all about genetics. The company has in-house samples from about 100,000 citizens, which covers roughly 1/3 of the nation. There is a statistical technique called imputation, which can be used in 2-steps. You can use it by having information for the whole gene sequencing from an indi-

vidual and extrapolate into other individuals whom you only have limited amount of genetic information, a blood sample for example. This is the first step, and imputation in this manner is quite secure; it is around 99%. The second step of imputation is to use, again, the whole gene screening of an individual, and using that information along with the genealogy of an individual of known relationship, and through imputation you can obtain the genetic constellation of the second individual who is not participated in the research. This is now debated in our Parliament regarding a new legislation allowing or not allowing this to happen. The projects that use this genetic database is supervised by the Data Commission and the Ethics Committee, so the use of this genetic database does not cause any problems.

[Slide 10] The third database contains health information provided by the individuals participating in specific research projects. They gave explicit consent as well as bio-samples and blood samples, along with their general information. This, too, does not cause problems because it is inside the framework of the Data Commission and the Ethics Commission. However, when it comes to the CHD, a problem arises.

[Slide 11] The idea of the CHD was first presented in 1998. The idea was to extend the database inside the deCode Genetics to incorporate all health information of every citizens. The company presented the idea to the Department of Health with political backup. The politicians worked for a speedy process inside the parliament and presented a proposal for a new legisla-

Health information database of the company

Lifestyle and medical history from each participant in the various projects

Encrypted data obtained by explicit consent

Each projects needs approval from the relevant Research Ethics Committee.

The number of individuals in the genetic as well as the health information database is around 100,000

Slide 10

Centralized Health Database (CHD)

- To extend the database of the company to include **all** health information from **all** health institutions in the country
- The company presented the idea to the Department of Health and had political backup of the prime minister
- A proposal for a new legislation was presented and the plan was for a fast process in the parliament
- The idea created fierce opposition by the research community as well as by the doctors

Slide 11

CHD - content

- Existing as well as new information should be moved to the database from health institutions.
- Originally, the idea was to use all data found in health records, irrespective of origin. This was later modified.
- Not only precise data (numbers etc) but also products from text.
- After processing, information would be sold to researchers.
- Health authorities would however receive information for free

Slide 12

Arguments for the CHD

- To create scientific knowledge on health by using data mining to find unknown correlations
- To create jobs in research
- To create revenues for the society
- To create revenues for the company

Slide 13

tion in the spring of 1998. However, their plan did not work due to the fierce opposition by doctors and research committees in general.

[Slide 12] In the proposal of the CHD, both the existing and future information will be transferred from health institutions to the CHD. Some of the information at that time were already stored as electronic data, but others were still paper-based. The original idea was quite far-stretching, attempting to put all information from heath records—not only the accounts of doctors but nurses or social workers, and even hospital priests. But soon, those who proposed the idea realized that the idea was not practical, and during the next 6 months, some changes were made.

The idea was not only to enter numbers, but also to produce *products* from *text*. After processing inside the database, pieces of infor-

mation can be sold to anyone who is willing to purchase and meet the standards. That was to be accounted for by independent regulatory committees. One of the most notable event was that the Minister of Health expelled the existing Ethics Committee and produced a new one—so the debate extended to the worlds of research, ethics, and politics. One of the ideas was for the health authorities to have free access to the information; they already had plans of a mutual health records for the whole population.

[Slide 13] There were some arguments supporting the CHD. It would create scientific knowledge on health by using various data mining to find unknown correlations. It will also create jobs in research communities. It will create revenues for the society, which was one of the most popular arguments for the CHD. The deCode Genetics, of course, will gain revenues

Arguments against the CHD

Too many practical problems in creating usable information.
Unthinkable for doctors to register information from and of their
patients that a third party would use and sell:
    Hence, most doctors were opposing the idea and the
    Icelandic Medical Association was supporting them
Difficulties in securing the rights of patients (the consent issue).
Difficulties in securing the information inside the database
    (technical issue)

Slide 14

The "battle" against the CHD

- The IcMA was leading the battle but the law
  was passed with many changes 6 months later
  than the original plan.
- After passing of the legislation, many ethical
  and practical issues remained problematic for
  the doctors and the battle continued.
- IcMA asked for support from the WMA which
  subsequently was opposing the idea of the
  CHD in the strongest terms.

Slide 15

from the CHD, but this point was not put forward very much in the debate.

[Slide 14] There were also arguments against the CHD. There were too many problems in creating useful information. It was quite unthinkable for most doctors that their patients' information will be sold to third-party companies by a private company every time they see a patient and put information in his/her record—just unthinkable for the majority of them. So, those doctors fiercely opposed the idea through the Icelandic Medical Association (IcMA). There were, of course, the issue of informed consent since it would be difficult to secure the right of patients. There were technical issues as well since it would be difficult to securely store only correct information inside the databases.

[Slide 15] So, the battle started. We managed to delay the legislation by around 6 months, and the bill was changed drastically from the original plan. But still, the bill passed, leaving many ethical and practical issues unsolved. So, doctors were not confident of its implementation. The IcMA sought support from the WMA, this topic received serious consideration inside the WMA. In meetings after meetings, committees and workgroups were presented with this issue, and both the president and CEO of the WMA visited Iceland twice. The effort continued for 4 years, until the WMA adapted the *Declaration on Ethical Considerations regarding Health Databases* in 2002.

[Slide 16] Allow me to review the informed consent issues. The deCode Genetics' first idea of consent was not to require any consent, but

The consent issue

- First idea:
    – No consent
- Second idea:
    – Presumed consent. All living individuals could opt out
- The company never accepted the third idea of
  informed consent put forward by the IcMA and
  others.
- The company lost the case of no consent for
  deceased individuals in the supreme court.

Slide 16

it was then changed to presumed consent for the living individuals. The company never accepted the third way of informed consent put forward by the IcMA and others. Then, the company run into a problem. A daughter to a deceased father took the case to a court, claiming that she should be asked whether or not her father's information should be entered into the database. She won the case in the supreme court, which meant that there is a serious issue in accessing the information that were collected from deceased relatives of living individuals, which are already contained in the database. That was a huge blow for the company.

[Slide 17] There were also technical issues. After the bill passed, the company started to make contracts with various health institutions in order to establish the database. Most of them participated, but some that were reluctant were

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Technical issues

- After passing of the law on the CHD, the company started to make contracts with various health institutions and to establish the database.
- Some health institutions were reluctant to make a contract on passing over patient information but were pressed by the health authorities
- The Data commission was following the technical issues which were more difficult than anticipated
- The Company ran out of money and the CHD was never realized

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Lessons to be learned

- New and bold ideas affecting many should never be processed fast, there should be time for reflection and dialog
- Ethical issues are particularly vulnerable and need to be addressed thoroughly
- Fierce opposition (needed in this case) create long time consequences:
  - Real progress becomes slower
  - Barriers are raised causing unintended problems

Slide 18

Lessons to be learned - ethics

There are important ethical issues in creating and using big health databases.

It is important to create a balance between patient rights for consent/information and practical issues.

In reality, the practical issues tend to override patient rights. This needs to be kept in mind.

The people needs to have trust on the safeguards and use of health data

Slide 19

The situation 16 years later

- The central patient health record planned in 1997 by the health authorities has still not been realized.
- Data protection is stronger in the health service than in other sectors of society, sometimes creating problems and always creating complicated processing.
- However, the databases that already had a firm ethical and technical basis and were not questioned are now a strong basis for research.

Databases are very strong tools for research, but handle with care!

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pressed to participate by the health authorities. The Data Commission worked hard to find an acceptable technical solution. But these technical problems were not resolved after 2 years, and the company run out of money. So, the CHD in Iceland was never realized.

So, this is what happened in the past. Now, let me talk about the lessons to be learnt. **[Slide 18]** New and bold ideas affecting many should never be processed fast; there should be time for reflection and dialog. Ethical issues are particularly vulnerable, and need to be addressed thoroughly. Fierce opposition, as in this case, creates long time consequences. Real progress in the technical field becomes slower because there are so many obstacles standing on the way. Barriers are raised causing unintended problems.

[Slide 19] Ethically, there are considerable ethical issues creating and using big health data-

bases, and I know that this has been the main topic of this seminar in the last 2 days. It is extremely important to create a balance between patients' rights for consent/information and practical issues. Sometimes, practical issues tend to override patients' rights—but we need to realize this tendency and be aware of the balance. This was an issue in my country 12 years back, but it is a hot issue today in some other countries. For example, the UK government has plans on population-based health information databases. In Denmark, there are several nationwide databases covering many deceased individuals, and the government now has a plan to combine these databases for the purpose of creating jobs and selling the information. Most important of all, people need to be able to trust the safeguards and use of health data. We must not forget that it is easy to lose trust but difficult

to regain it.

[Slide 20] Lastly, let me summarize the situations in Iceland 16 years after the CHD was proposed. It was 1998 that the CHD was planned, and it is now 2014. The CHD was never realized. Actually, there were plans in 2007 or 2008 to reinstate this 10-year old idea, but in another form. It was not realized because of the economic downturn, but the plan is still there, and it will be reinstated in the coming years. In my country and some neighboring northern countries, it seems that data protection in the health service is stronger than in other sectors of society, always creating problems and complicating a process. However, we also see that some databases have a firm ethical and technical basis. There are quite many of those, and they were not questioned.

Databases are very strong tools for research. But we must handle with care!

ICT and Healthcare in Korea: Present and Perspectives[*1]

Dong Chun SHIN[1]

I believe this topic includes a wide range of issues, but the time is limited. So, I would like to refer to the questions that were raised by the Japan Medical Association to organize my presentation so that my presentation will be more relevant to this occasion. **[Slide 2]** Those questions were: 1) Present progress of Information and Communication Technology (ICT) in the health care area in my country, 2) current status of privacy and personal information protection, 3) the numbering system, and 4) merits and demerits of healthcare supported by ICT.

[Slide 3] Upon reviewing these questions, I have organized my presentation into 3 categories: 1) Progress of ICT in the healthcare sector in Korea, 2) current status of privacy and personal information protection, 3) and the merits and demerits of ICT in healthcare.

[Slide 4] Now, the first part; the ICT progress

in Korea. Let's start from 1988. **[Slide 5]** We made the national health information network plan in 1988, however there were not very many

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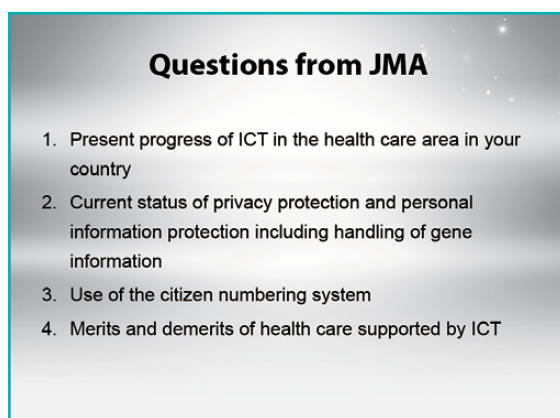
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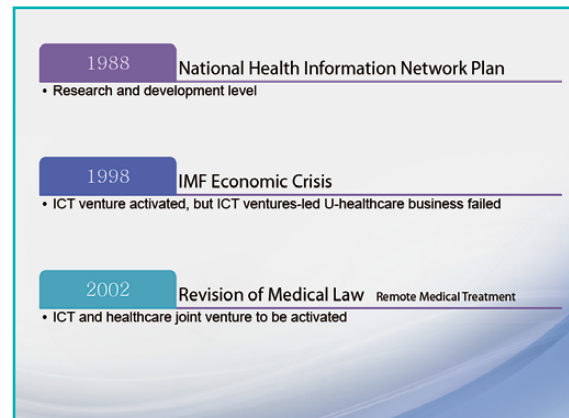
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activities to be implemented at that time. Ten years later in 1998, the IMF crisis occurred—it was the first serious economic crisis that Korea experienced, and it shook our whole country economically. Paradoxically, joint venture companies of information technology (IT) and ICT were also formed around this time, and they were blooming, too. However, most of them collapsed eventually. Back then, they probably saw the crisis as the real opportunity, so they tried again and again. The national slogan in those years was, "Our country, Korea, cannot get behind in IT and ICT in the world." The country believed that we were behind in industrialization in the modern society. That drove us to the current status, and now, Korea is one of the most advanced ICT country in the world. The efforts and experience over the years provide us with many technological tools. However, we do not necessarily have enough safetyguards to use ICT in the health fields. The remote medical training was legally accommodated for the first time in 2002; I will talk about this topic in the next slide.

[Slide 6] The Ministry of Health and Welfare of Korea has implemented several actions since the mid 1990's. The Health Care Information Strategy started in 1995, and the medical law was revised to accommodate the medical remote medical training in 2002. In 2003, the Ministry formed the advisory committee for ubiquitous healthcare system (called U-Healthcare) and provided some seeding money to develop detailed plans. The development of the electronic health/medical records (EMR) system by the government started in 2006. However, the private sector
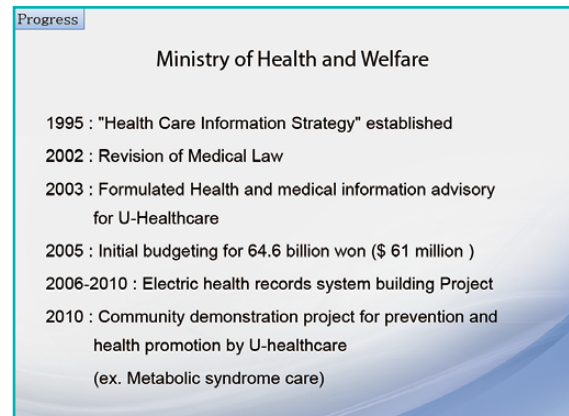
like my university hospital, the Severance, had already developed it in early 2000. In 2005, we made an ubiquitous system in the Severance Hospital, which we called the U-Severance. In 2010, the government started conducting some demonstration/pilot projects to prove the cost-effectiveness of the ICT use in the healthcare sector. However, I believe it has not been very successful so far.

[Slide 7] Owing to the rapid development of ICT in Korea, most of hospitals and clinics have the tool to claim insurance reimbursement using electronic medical record system. **[Slide 8]** In addition, we have the drug utilization system checked by the ICT system to verify the proper use of drugs.

[Slide 9] Let's revisit to the law. As I mentioned in my previous slides, we had the first revision of the law in 2002 and revised it

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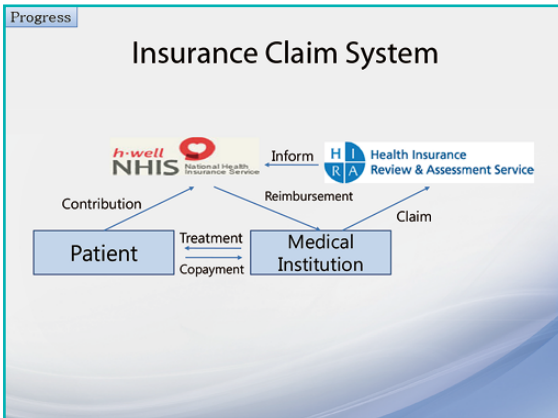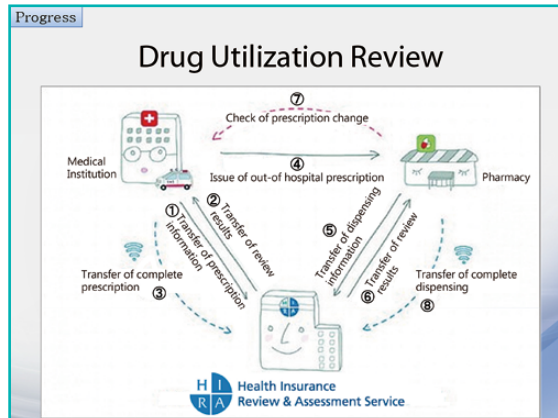
in 2007. This Medical Service Act Article 34 made the remote medical treatment possible, and stipulated that a distant doctor who gave a consultation to a local doctor has the same responsibility for most treatment of the patient. However, the recipient doctor—the "local doctor" who may be a medical doctor, dentist, or oriental doctor—has the primary responsibility, as stated in the paragraph. So, the local doctor working in the medical area has the primary responsibility.

[Slide 10] The Ministry of Health and Welfare categorized the ICT in healthcare into 3 groups. The u-Medical is for the rural and remote areas and targets inmates in prisons, military and police. The Ministry tried to conduct 5 demonstration projects until 2009 with other relating ministries such as the Ministry of Justice and Ministry of Safety and Public Administration, with the

cooperation from the municipalities. The second category is the u-Silver, which allows nurses visiting seniors at home or working in nursing homes to perform care upon consulting with medical doctors. The last category is the u-Wellness, which consists of community health promotion projects. These are the categories that the Ministry of Health and Welfare suggested until 2007, but they changed slightly in recent years.

[Slide 11] Next, let me talk about what is happening in the enterprises and institutions. There are many giant companies promoting healthcare and ICT. Nowadays, they have commercially come up with home network solution to help their business opportunities, and have built EMR systems for hospitals. The KT, a telecommunication company, is operating the smart U-Healthcare, and the LG and KT even transmit biological data via telephone line. The SK Telecoms is also

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operating similar systems, participating in governmental pilot projects and devising patient checking service systems.

Lastly, the Severance Hospital where I work now already set up order communication systems (OCS) since 2005—auto-communicating system, and EMR system, and ubiquitous system—that we collectively call the u-Severance.

[Slide 12] Let's move on to the next slide, which shows the situation in my hospital, the Severance Hospital. I would like to start from its history. We started in 1885, which is 129 years ago, from a traditional infirmary in a small house. Now, it has grown to this hospital with 2,000 beds. **[Slide 13]** It is a modern hospital, and now we almost finished constructing a cancer hospital as part of the Yonsei University Severance Hospital System on the other side of the main hospital. The cancer hospital is almost 70% of

the size of the main hospital. **[Slide 14]** We also have the Gangnam Hospital, which is the main branch hospital. You may all know about the Gangnam Hospital; it is located in the Gangnam area, and we have 12 other small community hospitals.

[Slide 15] We, the Severance Hospital, developed our own ICT, called the u-Severance. The Severance Hospital completed OCS in 1989, and established u-Severance in 2005 as I mentioned previously. This u-Severance include OCS, EMR system, full personal access communications system (Full-PACS), wireless local area network, and smart-card.

[Slide 16] Next category is the current status of privacy and personal information protection. Privacy is a big problem in Korea. **[Slide 17]** The number of complaint is increasing year after year; it exceeded 35,000 cases in 2009, which has
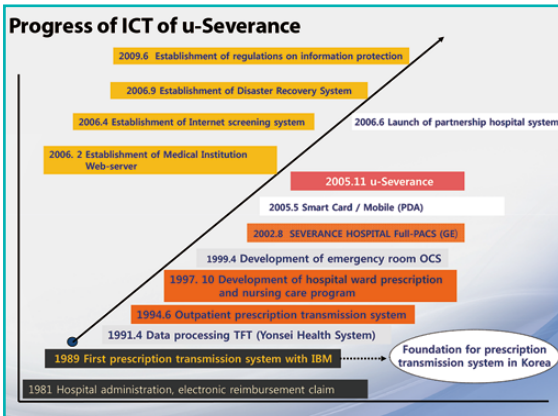
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roughly doubled compared to 2005. Types and numbers of violations in descending order are: 1) infringement of private information, 2) misuse of residential identification number by others, 3) transfer of personal information to others, 4) collecting personal information without consent, and 5) various technical mistakes.
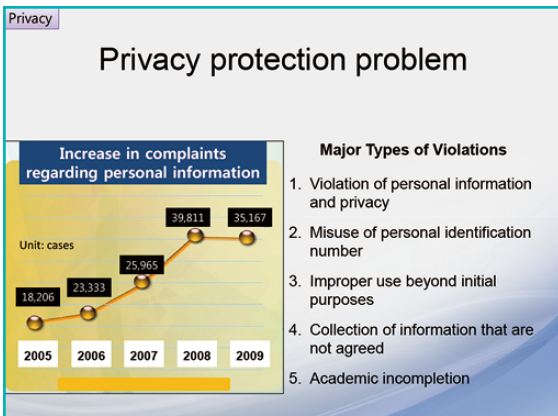
[Slide 18] I would like to introduce some detailed stories from actual cases. Bleach or theft of personal information has been committed by non-medical staff, in that they illegally inspected hospital's electronic records. Electronic prescriptions of 4,000 patients in a hospital were extracted by some clerks. Even the suppliers to a number of hospitals leaked patients' medical information from hospital management programs. As these examples suggest, there are many risks.

[Slide 19] So, the Korean government legis-

lated the Personal Information Protection Act in 2011, which strictly limits data exportation. One critical change that became mandatory was the

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change in the numbering system; it was changed from the resident identification numbers to the randomized secret codes. A new randomized number should be given for a clinical trial, as well. The same principle also applies to genetic research. The Bioethics and Safety Act was revised in 2013, and the monitoring by the Institutional Review Board is strictly enforced.

[Slide 20] In the Bioethics and Safety Act, it states that any research involving human subjects requires consent in writing, and that their personal information should be anonymized. So, the law was made to effectively protect people's privacy. **[Slide 21]** Under the randomized numbering system, we cannot see any personal information in the computer system; only dates of visits and some other numerical data. **[Slide 22]** The consent form for genetic research also has been strengthened, **[Slide 23]** and the target has been expanded to include not only genetic research but also the delivery of human bodies including genes.

[Slide 24] The last category is the merits and demerits of healthcare supported by ICT in Korea. I believe that Japan also has a similar healthcare system to Korea. **[Slide 25]** We have several challenges in our society for delivering good healthcare to the people. The number of people with chronic disease is increasing, and the concerns on wellness and prevention are rising. People demand proper assessment and good quality, as well as efficient healthcare delivery. Consumers are empowered, ICT is rapidly developing nationwide, and we all live in the aging society. These factors demand new ways of healthcare delivery. We all agree to that, but how can we achieve it?

[Slide 26] The government is always con-
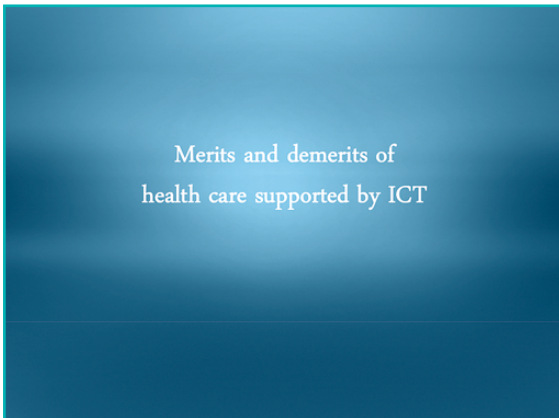
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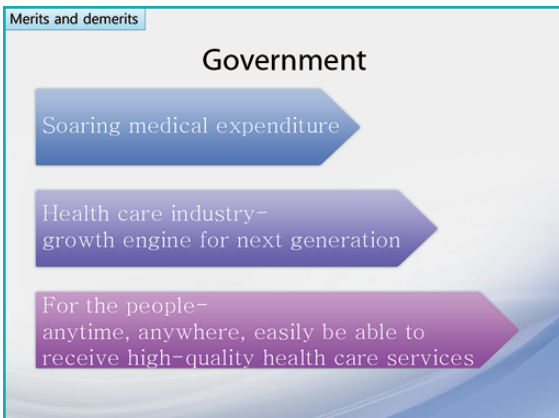
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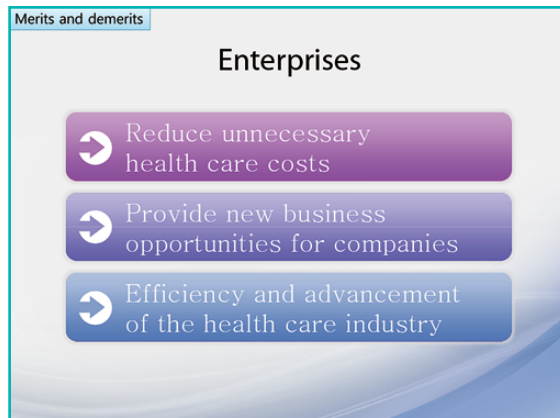
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cerned about the soaring medical expenditure because it is ever increasing. They also care about the healthcare industry because it should be one of the major growth engine for next generation's society. The government tries to provide high-quality healthcare to the people anytime, anywhere, although it is very difficult to achieve.

[Slide 27] How about private enterprises? I believe that enterprises have now become the major stakeholders in ICT and health care fields in every nation. Enterprises say that the ICT introduction in our healthcare system will reduce the healthcare expenditure by reducing the indirect costs such as transportation and labor time. They also say that it will bring new business opportunities, increase efficiency, and advance the health care industry.

[Slide 28] According to the data of the Min-
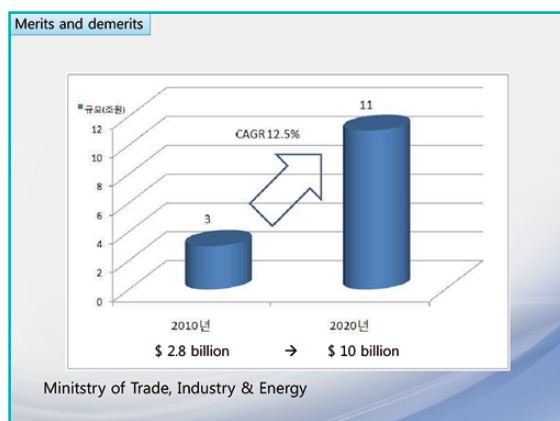
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istry of Trade, Industry and Energy, the cost of ICT in 2010 was about 3 billion USD, but it is estimated to increase to 10 billion USD in 2020.
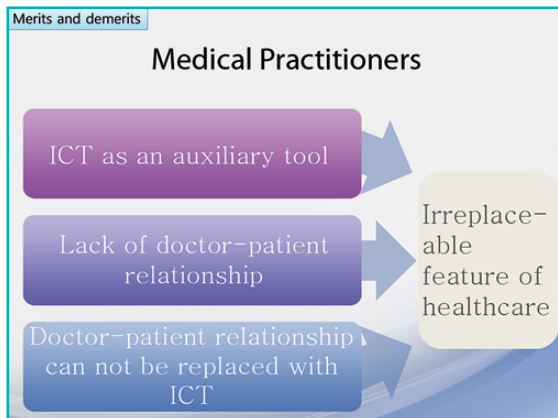
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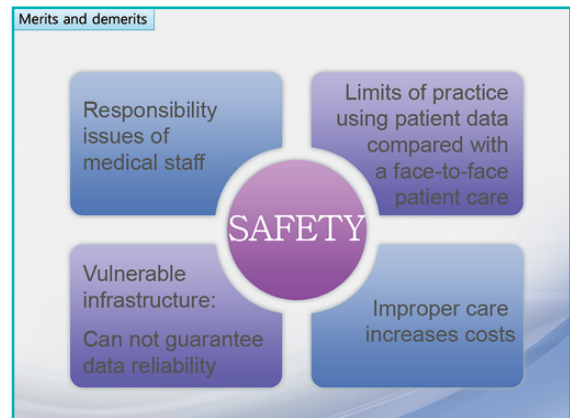
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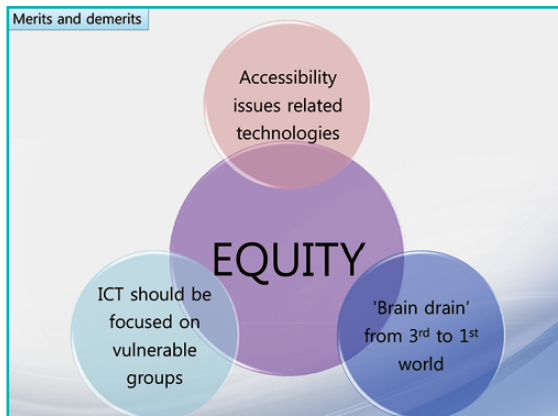
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So, there is a 7 billion USD worth of market waiting for the enterprises, and they are well prepared to fill in this growing market. That is why the ICT development is now one of the most critical issue in Korea.

[Slide 29] However, medical practitioners believe that ICT should be regarded as an auxiliary tool, and that the excessive development of ICT can damage the doctor-patient relationship. The doctor-patient relationship is an irreplaceable feature of healthcare that cannot be replaced by ICT. **[Slide 30]** In addition, the patient safety should be the utmost importance. Medical practitioners and staff have certain professional responsibility. ICT itself is very vulnerable against hacking, for example. ICT may provide patient data, but face-to-face patient care is very important. The ICT-oriented healthcare can lead to improper services, which can increase costs, too. **[Slide 31]** We should also consider the issues of equity, such as technological accessibility or the care for vulnerable group. Another global concern is the 'brain drain' issue from the third to the first world. The excessive advancement of ICT in the first world could force the third world to stay in the low-level heath care.

[Slide 32] Countries around the world have carried out cost-effectiveness studies associated with the ICT implementation. There have been no definite evidence of its cost-effectiveness, and the study on health care cost in European countries concluded in 2008 that the evidence was insufficient. In the developed countries, limited enforcement in education and training is the limiting factors. **[Slide 33]** So, the ICT companies tried to find evidence in the third world, but the third world has serious transition issues. The

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third world requires substantial improvement in healthcare infrastructure, but the introduction of u-Health would dilute their own healthcare needs. So, they faced a completely different problem.

[Slide 34] In view of the situation in other countries, the Korean government proposed specific categories to start the ICT implementation. In their plan, they will start at local small clinics for patients with chronic illness or disabilities or those who live in remote areas. At hospitals and large clinics, they will start from the patients who require post-operation care and the people in special institutions such as the military. The government also proposed to work with specific cases involving crime at specific clinics, such as domestic violence or sexual assault.

[Slide 35] However, the Korean Medical Association (KMA) strongly opposed these ideas as the tele-medicine that the government is pursuing damages the fundamental aspect of health care, which requires face-to-face interaction between patient and physician. KMA is particularly against the current tele-medicine system because issues such as patient safety and legal liability were not assessed or examined during the preparation process.

KMA believes that patient safety, efficacy and legal liabilities related with tele-medicine are issues that cannot be compromised because it involves public health and the physician's professional rights. In particular, tele-medicine that allows the involvement of private companies such as health management service providers should never be permitted.

As you may know, healthcare endorsement is quite low in Korea compared to the quality of care provided. Roughly speaking, Korean medical doctors work 3 times more for 3 times less income when compared to the OECD averages. General people in Korea are very much satisfied with their current situation, and the Ministry of Health and Welfare is proud of establishing and managing this good health care system—but medical doctors have to take on all the burdens in Korea. So, in the future ICT issues in Korea, we will have to be wise enough to come up with a win-win situation for the government, patients, and medical practitioners such as ourselves.

Thank you very much—*Arigatou Gozaimashita.*

Healthcare Information Technology and United States Healthcare*1

Robert WAH[1]

[Slide 2] As Dr. Shin of the Korean Medical Association mentioned, we were given several questions to answer in our presentations. I will also try to follow along the same questions that the JMA provided to us, the American Medical Association (AMA).

As way of background, I am a reproductive endocrinologist dealing with infertility and hormonal disorders in women. I live in the Washington DC, and I practice at the National Institute of Health in the Walter Reed National Military Medical Center in Bethesda, Maryland. I have spent my entire career taking care of women and their healthcare needs, and I have become very active in the area of Health IT in the last 10 years or so. I was the Associate Chief Information Officer through the US Department of Defense, where I worked as the lead doctor for the IT section, taking care of 10 million patients in 65 hospitals and 450 clinics worldwide. In 2005,

I was loaned out of the Department of Defense to the Department of Health and Human Services, where I was the first Deputy National Coordinator for Health IT for the United States. In that role, I was the Chief Operating Officer, setting up a new office in the United States, called the Office of the National Coordinator for Health Information Technology. As the Chief Operating Officers, my job was to set up the new office, develop the strategy for the United States for the use of Health IT across the country. We had a new office with very little money—and we said "we have big dreams and no money." I'll tell you later what happened at our office.

In 2006, I left that office and retired from the military after 23 years on active duty service in the United States Navy. I am currently the Chief Medical Officer at the Computer Sciences Corporation. We do about $2 billion of work per year in Health IT around the world, and some
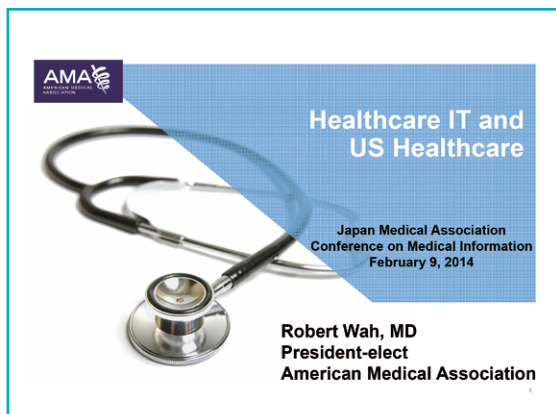
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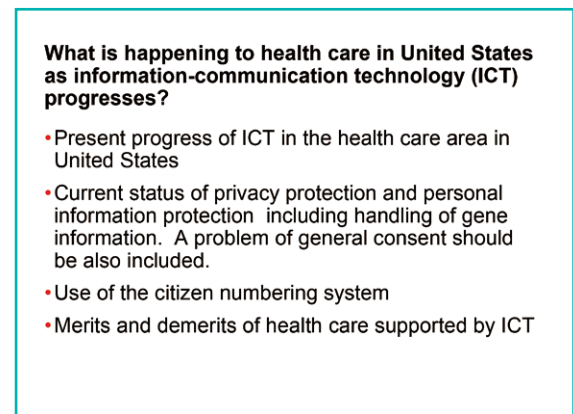
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of the largest deployments of electronic medical records were done by my group. We deployed electronic records to 2,500 outpatient clinics in the United Kingdom, taking care of 35 million citizens all on the same electronic health record system. So, this is the basis by which I present this information to you, not only about the United States but also about the global work in Health IT.

[Slide 3] It's my belief, from my experiences, that the role of Health IT is that it can actually transform healthcare by delivering better information for better decisions. Everybody in the healthcare space can use better information. Patients need better information. Doctors need better information. Government and insurance plans need better information. Researchers need better information to find new discoveries to help us take better care of our patients.

Technology, I believe, is a tool that helps us as doctors take better care of our patients. Dr. Shin talked about the concerns about interfering with the doctor-patient relationships. We as physicians must make sure that we use technology as another tool, just like we do in the operating room or in the clinic to take better care of our patients. We must not let the technology take over us. We must remain masters of the technology and use it as another tool to help us take better care of our patients.

Let me talk about what has happened in the United States in the last several years. As I said, I set up an office called the Office of the National Coordinator in Health Information Technology in 2005. I left the office in 2006.

In 2009, the United States passed a new law called the Health Information Technology for Economic and Clinical Health Act (*a.k.a.*, the HITECH law), and that office that I started in 2005 was given $2 billion USD to do its work. I did not have $2 billion when I started the office in 2005—the budget was much, much smaller than that. In 2009, we also passed a law to provide incentive money for doctors and hospitals to move from paper records to electronic records.

[Slide 4] I made this slide around 2009, which describes what would happen over the next 10 years in the hi-tech path. I expected 3 waves of investment to happen in Health IT.

First, there is the investment in electric health records (EHRs), where we are going to invest somewhere in the neighborhood of $30 to $40 billion to get doctors and hospitals off of paper records and onto digital records. That is still happening today; doctors can qualify for between $40,000 and $60,000 per doctor to leave paper records and move to electronic records. Hospitals are given incentives in the order of $2 to $10 million to go from paper records to digital records. So, in total, something on the order of $30 to $40 billion will be spent on the migration from paper records to digital records. Now, the Office of National Coordinator also has $800 million to a billion to network these digital records together into what we call the Health Information Exchanges, or HIEs, which is the second wave of the investment. So now, we are going to get off of paper onto digital records, and we are going to network those records together
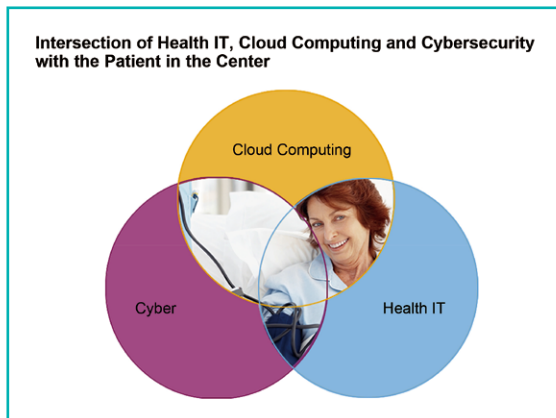
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and form these HIEs. It was my belief in 2009, that we are going to see the third wave of investment happen right around now. Now that we have digital information that are networked together, we would want to analyze that information and support decision-making to help physicians take better care of their patients. The first 2 waves have already happened, and now, we are starting to see the rise of the third wave.

[Slide 5] It is also my belief that we are seeing an intersection and overlay of 3 major technologies. One is Health IT, and the second is a new technology called Cloud Computing. The third technology, and a very important component of this intersection, is what I call cyber security or technology, to prevent the release or hacking of information. Our patients is in the middle of this intersection, and we should never forget that that is why we are doing all these things—we are not doing our work for technology sake, we are doing it so we can take better care of our patients.

[Slide 6] Let me break each one of those intersections down, and just talk briefly about what each means to me as a practicing physician using technology to take better care of my patients. Cloud Computing has a lot of different meaning to a lot of different people. In many ways, it involves being able to episodically use just the right amount of computing power that you need—not too much, and not too little. It also means that information is now much more fluid and moves around in new ways that we never were able to do before. In the old classic, there was a big box inside of a big building, called a computing center. Now, with Cloud Computing,

the computing can happen very far away from where the user needs to have the information. By separating where the computing happens and where the user utilizes the information, it gives us many new opportunities to change the way we use information and take care of our patients.

One example of that is, all of our devices—a computer in your desk or a handheld in your pocket—now can serve as a window or a viewer into the computing activity, which can be happening hundreds or thousands of miles away from where you are using the information. So, as I said before, there is a continuum now. It could be a desktop computer or a borrowed computer of your aunt's house. You could be in the office or a hotel or at an airport. You can be on your handheld or tablet. It does not matter where you are; you have access to new information because these devices are just a viewer into the computing that is happening somewhere else.

Let me change gears now, and talk about cyber security. Dr. Ishii and Dr. Snædal both mentioned our concern of our patient's privacy, of the important information that they have given us. We, as physicians, have always been what I call *data stewards*. Our patients come to us, and they tell us some of the most confidential and private information about their lives. They do that very willingly because they trust us as physicians, to hold that information private and confidential. They know that telling us that private and confidential information will help us take better care of them. So, for centuries, physicians have been entrusted with private and confidential information. We, as physicians, must

Medical Data Breaches Cost Billions

- *71 percent of health care organizations suffered a data breach in the last year*
- Data breaches in US alone Cost between $4.2 billion and $8.1 billion a year, or an average of $6.5 billion
- Most breaches were the result of employees losing or having their IT devices stolen or other unintentional, but ill-advised, employee action according to 49 and 41 percent of respondents
- Shoddy security from partners and providers, including business associates, according to 46 percent of participants, was another significant reason
- Once a breach is discovered, 83 percent of hospitals reported it taking one to two months to notify affected patients. Nearly a third, or 29 percent, admitted that breaches lead to cases of identity theft, up 26 percent from the previous year

Graphic Courtesy World Privacy Forum, Aug. 2011, Based Upon Information from the U.S. Federal Trade Commission.
Source, Dec. 2011, Second Annual Benchmark Study on Patient Privacy and Data Security conducted by the Ponemon Institute and sponsored by ID Experts.

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continue to protect our patient's private and confidential information, even though that information has now left paper and is now on a digital platform. I will tell you, however, that now that we have moved to a digital platform, there are new threats to the privacy and confidentiality of patient information.

When we used paper to keep patient information, we had to try to keep it private inside our offices or inside our hospitals. That was thought to be fairly private. If you think about it, however, in some ways paper records are not protected very well because there is no record of who looks at a piece of paper. Anybody—the doctor, the nurse, the front desk clerk, or even the janitor who works in the building—can look at a paper record, and there is no trace of that. So, in some ways electronic records give us a new layer of protection, because we can protect the digital information by making sure there are digital footprints by anybody who looks at a digital record.

Now, some of the things that we talk about in terms of privacy and security are along the lines of protecting the patient's private information. For example, I am an obstetrician gynecologist, so many women are very concerned that their reproductive history may get out. If they have had pregnancy termination or sexually transmitted diseases, it can be potentially very embarrassing and damaging if this information gets out. In other specialties, for example if a patient is on a psychiatric medication or has had counseling for psychiatric diseases, it is often very concerning for patients if that information

were released.

So, patients are very concerned about breaches. If you ask them about digitalization of healthcare or Health IT, their number one concern is that their health information will show up on the internet. We have all seen that credit card information can show up on internet, but health information can be very much more damaging if it is exposed. If your credit card shows up on the internet, it is a big problem, but a solvable one. It might take a couple of years, tons of phone calls, and many hours of work, but you can overcome the damage of your credit card information showing up on the net. However, if your critical health information, *i.e.*, your diagnosis of HIV infection, the fact that you are on psychiatric medication, or the fact that you have a sexually transmitted disease, shows up on the internet, that is a bell you cannot un-ring. Patients know that, and they are very afraid. So, they expect us in the health field to take very, very careful care of their private and confidential information. So, that is one part of privacy and confidentiality about the Health IT movement that we are seeing.

Now, I will tell you that there is a whole another side to that. **[Slide 7]** This is a list of some of the medical data breaches that have occurred in the United States in 2011. It is very widespread and expensive. Just very recently in the United States, we have heard a lot about organized crime trying to break in and get credit card information. In the holiday season in the last winter, a major store in the United States called Target had somewhere between 40 and 100 million records stolen by criminal elements who wanted to gain access to the financial information in those credit cards and debit cards. I believe it made the newspapers everywhere around the world. In healthcare, those same criminal elements are trying to get your health information as well. They do not care about your diagnosis of HIV or your sexually transmitted history; their interest is in the street value.

[Slide 8] On the street, the criminals can sell credit cards for about a dollar per credit card number, but they are currently selling health records for $15 to $20 per record. Health records are much more valuable than a credit card number, because a health record is so rich in information about a patient that you can create a very strong identity with that health information,

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and with that strong identity you can earn much more in financial fraud than you can with a single credit card number.

So, we are now under attack in healthcare by the same criminal elements that are attacking financial information, and we in healthcare need to start utilizing the same industrial-strength technologies that are used in the financial system. Granted, those technologies are not very good, because we still see breaches like we saw at Target where 40 to 100 million records were accessed. Nevertheless, across healthcare we are not anywhere close to the cyber security levels that banking and financial institutions use, and we in healthcare need to start thinking about the fact that we are under attack by the same criminal elements that those financial institutions are being attacked by. My point is, we need to be mindful of our role as *data stewards* in protecting the privacy and security of our patient's information, not only for their health reasons but also to fight against these criminal elements that are seeking to attack the massive information that we have built up in healthcare.

[Slide 9] My last comment about security and privacy is that many people see privacy and security as a burden, as one more thing they have to do, and that it is a cost. Let me try to make a different argument for you. At the company I work at CSC, we protect the secrets for all the 3-letter organizations in the US governments, such as the CIA, the NSA, and the FBI. The cyber security experts of my company tell me that we need to think of security not as a burden but as an enabler, because without secu-
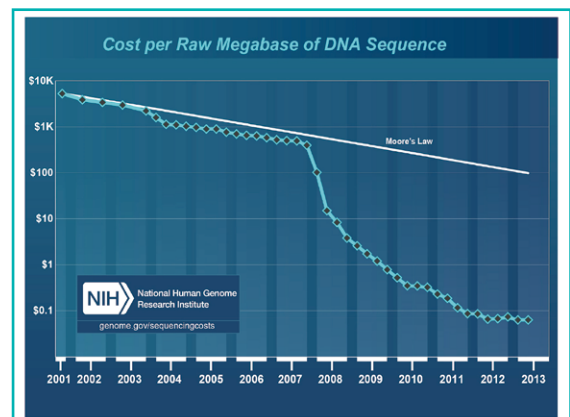
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rity we will not be able to have a network. If patients are concerned that we do not have adequate security, they will stop giving us information. Then, the networked electronic digital platform we talked about will cease to exist, and all those benefits that we hope to reap from having access to that information will go away. We need to think of security as an enabler that makes patients, doctors, and governments comfortable in having a networked digital information system. So, we need to stop thinking about security or privacy as a burden or cost. We need to consider it as an enabler that gets us where we want to be, which is having networked digital information available to help us take better care of our patients.

I want to switch gears now because we were asked to talk about genetic information. **[Slide 10]** This is a slide presented by the National
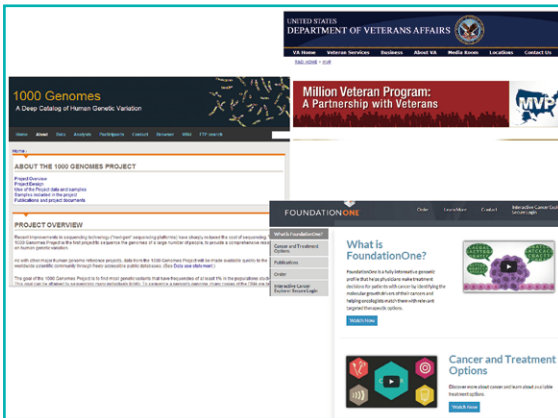
Slide 11

Slide 12

Institute of Health, one of our premier research institutes in the United States, which describes the rapid decline in the costs of performing genetic analysis. We use this line that represents the Moore's Law as the reference. He was one of the co-founders of the Intel Corporation that makes the chips in many computers. A long time ago, he made a statement that every 2 years the computing capacity on chips would essentially double. For years and years, this Moore's Law has almost been like the law of gravity—every 2 years, our computing power has doubled. If you think about it, that is a tremendous achievement. We have never doubled anything every 2 years except for computing power.

Let's look at what we have been able to do in genetic analysis. The cost of performing a DNA sequencing has dropped precipitously in just last 7 or so years, to the point now that there is a new proliferation of companies and activities based on the fact that we can get very rich information from genetic analysis. **[Slide 11]** I will show a series of slides very quickly to give you some examples. I do not have the time to go into a lot of detail, but I wanted to show you some of the activities that are happening around the United States. The Veterans Administration,*2 which is for all the people who have left the military, are seeking to get the DNA from 1 million veterans to start a DNA database of a million veterans. There is an international project called 1000 Genome Project,*3 which is starting a library of genetic analyses from 1,000 people
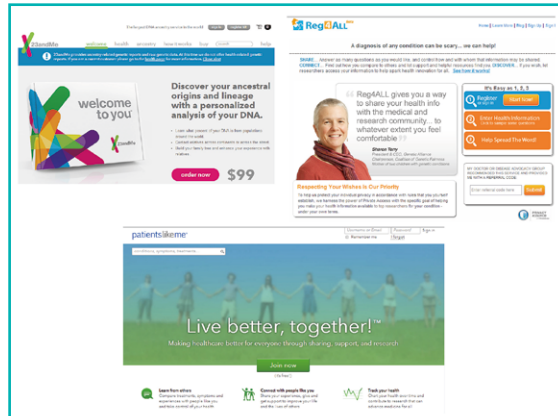
Slide 13

with diseases to compare against when we find out the genetic makeup of other individuals. The FoundationOne*4 is another group that specifically started looking at cancers to find out if we can tell the genetic makeup of a cancer cell in order to figure out what is the best treatment for that cell—not all the other ones, just that one particular cell. **[Slide 12]** The Partners Healthcare*5 is a hospital system at the Harvard Medical School, and they are now offering services that are based on the entire genome analysis of a patient. The Illumina*6 is another group that is seeking to help doctors take better care of their patients with a definitive genetic analysis of the entire genome.

[Slide 13] Now, I want to switch to another slide, which talks about what patients think

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*2 http://www.va.gov/; *3 http://www.1000genomes.org/; *4 http://foundationone.com/; *5 http://www.partners.org/; *6 http://www.illumina.com/.

about their own private information. As I said before, patients are very concerned about their information showing up on the internet. However, there are some interesting activities on the patients' side, which tell me that there is a change in the way we need to think about patient's information as well. The first example I would like to share is a company called 23andMe.*[7] They send you a small kit in the mail, and you take a swab of your inside cheek and send it in, and for $99 they will give you a genetic analysis not of your entire genome but just certain parts of it. They were just asked to stop being a healthcare advisor, and they are now only allowed to tell you about your relatives that have the same kind of genetic changes that you have. So, patients now have the ability to obtain genetic information about themselves and their families for $99.

This group here, Registrations for All, or Reg4All®,*[8] is a company where patients are willingly giving information. It is not necessarily genetic information; it can be a history of their diseases, their surgeries, or their medications. Patients share those information to see if there are other patients like them who can share information, and figure out how their disease, either chronic or serious, can be bettered by sharing information with others.

The last one I would like to mention is a company called PatientsLikeMe,*[9] which was started by an engineer of the Massachusetts Institute of Technology (MIT) whose brother had been diagnosed with a fatal disease called amyotrophic lateral sclerosis. As those of you in neurology know, this is a fatal, debilitating disease, where you lose the function of your muscles very gradually at first but then very rapidly, so you can no longer move or speak, and ultimately you can no longer breathe. The brother started a website because he was very frustrated that there were no good therapies for his brother's fatal disease. So, he started up a website called PatientsLikeMe, and other patients with this unusual and fatal disease started posting very personal information. They would post their X-rays, blood test results, and doctor visit summaries—to help see the other patients out there who had the same disease, that maybe others had a different outcome or a new success.
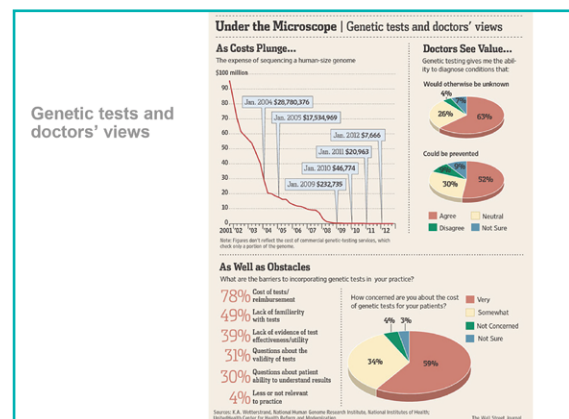
Slide 14

This MIT engineer adamantly believes that privacy laws are killing patients every day. He says that the fact that we keep all this information private rather than sharing is killing other patients around the world. In his belief, interestingly, the last thing you worry about when you are sick is the privacy of your information. So, when you have a fatal cancer or disease that you know it is going to kill you, the last thing you care about is whether or not other people know your private information. In fact, at that point, he encourages to share all your information, and see if others in the world have had a same disease but had more success than you have with other medications or other therapies. So, this website is a very open website where people share their most personal information, down to the degree of what they ate for breakfast or what their temperature was at noon. They are putting all up on the website, in the hope that somebody else could benefit from it or somebody would give them advice to help them. So, it is a total change in the way we see privacy and security. I believe that the difference is in the status of your own health; when you are healthy, you have a different perspective on privacy and security than when you are sick, especially with a fatal disease.

[Slide 14] This is a quick chart about what doctors in the United States think about genetic testing when asked by the Wall Street Journal. The first thing you see is how rapidly the cost of genetic analysis has plunged, even faster than

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*[7] https://www.23andme.com/; *[8] https://www.reg4all.org/; *[9] http://www.patientslikeme.com/.

AMA Policy on Genetic and Genomics

- D-460.971 Genome Analysis and Variant Identification Our AMA: (1) encourages payers, regulators and providers to make clinical variant data and their interpretation publicly available through a system that assures patient and provider privacy protection; and (2) encourages laboratories to place all clinical variants and the clinical data that was used to assess the clinical significance of these results, into the public domain which would allow appropriate interpretation and surveillance for these variations that can impact the public's health. (Res. 519, A-13)
- H-65.969 Genetic Discrimination and the Genetic Information Nondiscrimination Act Our AMA: (1) strongly opposes discrimination based on an individual's genetic information; (2) will pursue and support legislation intended to provide robust and comprehensive protections against genetic discrimination and misuse of genetic information; and (3) supports education for health care providers and patients on the protections against genetic discrimination currently afforded by federal and state laws. (CSAPH Rep. 7, A-13)

Slide 15

AMA Policy (Continued)

- H-460.905 Clinical Application of Next Generation Genomic Sequencing 1. Our AMA recognizes the utility of next-generation sequencing (NGS)-based technologies as tools to assist in diagnosis, prognosis, and management, and acknowledges their potential to improve health outcomes. 2. Our AMA encourages the development of standards for appropriate clinical use of NGS-based technologies and best practices for laboratories performing such tests. 3. Our AMA will monitor research on and implementation of NGS-based technologies in clinical care, and will work to inform and educate physicians and physicians-in-training on the clinical uses of such technologies. 4. Our AMA will support regulatory policy that protects patient rights and confidentiality, and enables physicians to access and use diagnostic tools, such as NGS-based technologies, that they believe are clinically appropriate. 5. Our AMA will continue to enhance its process for development of CPT codes for evolving molecular diagnostic services, such as those that are based on NGS; serve as a convener of stakeholders; and maintain its transparent, independent, and evidence-based process. (CSAPH Rep. 4, I-12)

Slide 16

the Moore's Law would have predicted. This chart stopped in 2012 at $7,000, but we believe the cost of a genome analysis would be a $1,000 or less in the next 12 to 18 months. That shows how rapidly the cost is coming down. So, genetic analysis will give us a whole new suite of information we never had before, which we can use to take care of our patients. These other charts are about what doctors think about in terms of genetic testing in particular.

[Slide 15] Now, I want to switch the topic and talk about the policies that we made at the AMA, specifically in the area of genetic testing and the use of information. I believe it falls into a couple of main areas. One is, we obviously want to be very careful that clinical information about genomes does not become too private and too proprietary, where a company is going to start making money because they have genetic information that they only share if you pay for it. We want to make sure that the genetic information is a much more open and shared, so that all of society can benefit from new discoveries in the area of genetic testing and genetic information. We also want to make sure that our patients are not discriminated against. Many times genetic information does not tell you exactly what is going to happen to you, but it might tell you that you are at increased risk of suffering a certain disease. So, there is a concern that patients will be discriminated against for having certain genes. If you have a gene that says you are at an increased risk for a disease, employers may fire you, or the insurance company may stop insuring you or may charge you more for your insurance.

The Future
Interconnected, Private, Secure Health Information Exchange
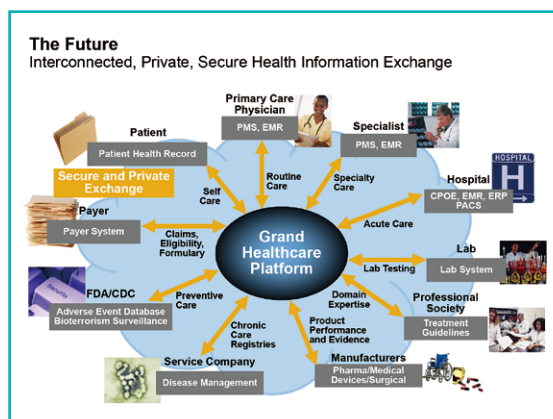
Slide 17

We consider that discrimination simply based on your genetic makeup is possible, and it concerns us very much.

[Slide 16] Another AMA policy I have here, again, talks about making sure that we as physicians embrace this new technology in a way that will help us take better care of our patients. That means training our new doctors in medical school, our existing doctors in practice today, and the rest of the medical industry about how we can really take advantage of this new source of information about our patients. So, this is a quick summary of some of the major policies that we made in the area of genetics at the AMA.

[Slide 17] In summary, let me just talk about what I see in the future of IT in healthcare. I believe that we are all going to start forming what I call the Grand Healthcare Platform, which is in the main circle at the middle of the
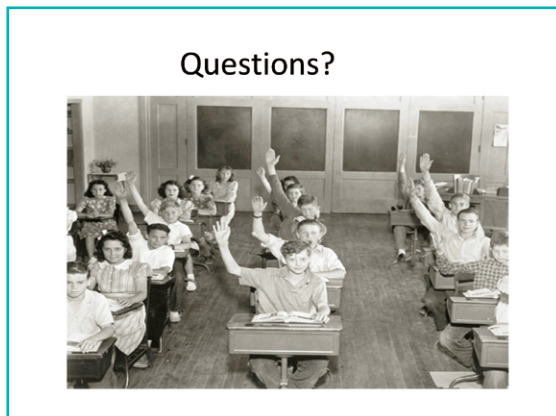
Slide 18

slide. It is not a physical place or a physical thing; it is a virtual pool of information. All of us in healthcare—patients, doctors, nurses, specialists, hospitals, labs, societies, manufacturers, government—are around the main circle. Everybody will want to contribute to the pool and take out different information from the pool, but we will be in and out of the pool all the time. The arrows pointing to and from the pool are the pipes that get us to and from this pool of information, and this is where I believe we can build industrial-strength cyber security to make sure that appropriate use of this pool is enforced. We have all the ethical and legal considerations that were mentioned by the 2 previous speakers. We need to make sure that the access to this pool is very controlled and secure, in both getting the information in and out. However, this pool of information is not going to be one big database or one big computer in the sky. It is going to be information in multiple places, but we can assemble it together as if it is one virtual pool using technology.

Soon, we will be going in and out of the pool to help us take better care of our patients. It may be to coordinate the care of our patients across specialists, learn new discoveries about how to take care of chronic or lethal diseases, or allow our patients to participate in their own care in ways they never were able to do before. So, this virtual pool of information is forming today, and we never would have been able to have that so long as we had health information solely on paper. We are living in an age that the paper-based system is giving away to a new digital system, and that digital system is now networked together forming this virtual pool of information. It is incumbent on us to use the cyber security technology to protect the virtual pool of information, or else the patients will not let us have it anymore. That is where I believe we are heading very quickly.

Conflicts between Public Car Insurance and Public Medical Insurance in Japan: International Comparison Survey

Kazuki SAKAGUCHI,[1] Koichiro MORI[1,2]

Abstract

This paper clarifies essential issues regarding conflicts between public car insurance and public medical insurance in Japan, presenting the findings of an international survey to detect similar problems in other countries and discussing possible options for the resolution of these problems. Three essential issues are important to note: (i) Different prices between the two systems of public insurance provide stakeholders with the irrelevant incentive to apply public medical insurance in the case of car accidents; (ii) Public medical insurance sometimes covers medical expenses due to car accidents, although it should not cover them in principle; and (iii) The costs are imposed on tax payers unconsciously when people use public medical insurance for car accidents. Five findings were obtained from the international survey: (1) Most countries have compulsory car insurance; (2) Private insurance companies manage the financial affairs of compulsory car insurance in most developed countries; (3) Fault for casualties is not considered in the compensation of medical expenses in most countries; (4) Japan is unique in that people can choose between the two systems of public insurance; and (5) Prices for the same medical services differ between the two systems of public insurance in only a few countries. In consideration of the above findings, we provide five options for the resolution of this issue from the viewpoint of victim relief.

Introduction

In Japan, two systems of public insurance can be selectively used for covering the medical expenses of casualties in car accidents: public car insurance (Compulsory Automobile Liability Insurance) and public medical insurance (Health Insurance, which provides universal coverage).*1 The two systems of public insurance are based on different laws. This choice of two systems of insurance is specific to Japan, and the situation brings about conflicts of interest among stakeholders related to the two systems of insurance. Some stakeholders have an irrelevant incentive to apply public medical insurance in the case of

a car accident in order to reduce the costs of public and private car insurance. People incur transaction costs through opportunistic behaviour due to this situation (Coase 1937; Williamson 1985).[2,3] In principle, car insurance should cover the medical expenses of car accident casualties. Thus, the conflicts arising from the choice of two systems of public insurance inflict costs on public medical insurance.

Certainly, the flexible choice is beneficial to casualties of car accidents because the two options enable them to easily cover medical expenses. In particular, fault for casualties should be considered and counterbalanced in Japan. Under the current system, the application of public

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medical insurance reduces the charges for casualties because the patient charge is 10-30% of the total medical expenses under public medical insurance. In addition, the amount of compensation may be maximized by using public medical insurance to cover medical expenses and public car insurance for consolation money and leave compensation, especially when the perpetrator of a car accident does not have private car insurance.

Nonetheless, there are complicated conflicts among stakeholders due to the choice of two systems of public insurance. Let us examine three conflicts here. First, the prices of medical services differ between public car insurance and public medical insurance. Prices in the case of the application of public medical insurance are lower than those in the case of the application of public car insurance. Therefore, those responsible for paying medical expenses have the incentive to apply public medical insurance rather than public car insurance.

Second, public medical insurance sometimes ends up covering medical expenses that it should not cover, although public car insurance should cover them in principle. When public medical insurance is used for covering these expenses, relevant documents on notification of 'injury and sickness by a third party act' should be submitted by casualties. Casualties, however, have little incentive to submit these documents. If they do not submit them, the medical expenses covered by public medical insurance cannot be charged to public car insurance. Thus, there are conflicts amongst the private insurance companies that are responsible for the management of finances for public car insurance and public medical insurance associations.

Third, there are conflicts between the ultimate financial contributors in the two systems of public insurance. Public medical insurance is financed by both insurance fees and taxes, while pubic car insurance is financed by insurance fees only. If public medical insurance pays for medical expenses that public car insurance should cover in principle, tax payers implicitly incur the costs without their realizing.

The purpose of this paper is to: (i) clarify essential issues regarding conflicts between public car insurance and public medical insurance in Japan; (ii) present the findings of an international survey to detect similar problems in other countries; and (iii) discuss possible options for the resolution of these problems.

Problems Regarding Conflicts between the Two Systems of Public Insurance

Impacts of conflicts

In this section, we show that the problems regarding the conflicts between the two systems of public insurance are not trivial. We calculate the annual costs that are inflicted on public medical insurance that should in principle be covered by public and private car insurance. The annual costs that are inflicted on public medical insurance due to these conflicts can be estimated at approximately 11.8 billion Japanese yen. In the following, we describe the process of estimation in detail and then consider its significance.

To begin with, let us calculate the annual total medical expenditure due to car accidents. Based on available data (General Insurance Rating Organization in Japan 2012), the average medical expense per car accident is 165 thousand yen, and the annual number of casualties of car accidents is 1,287,521.[4] Thus, we can estimate that the annual total medical expenditure is approximately 212.4 billion yen.

Next, we estimate the annual total medical expenditure that is applied by public medical insurance. Based on the same data (General Insurance Rating Organization in Japan 2012), 5.5% of the casualties of car accidents are hospitalized.[4] According to Japan Medical Association data (2012), 58.1% of inpatients and 17.2% of outpatients use public medical insurance in the case of car accidents.[5] Thus, the annual total medical expenditure that is covered by public medical insurance is approximately 41.3 billion yen.

Inpatients:
  6.8 billion yen $= 212.4$ billion yen $\times 0.055 \times 0.581$
Outpatients:
  34.5 billion yen $= 212.4$ billion yen $\times 0.945 \times 0.172$
Total:
  41.3 billion yen $= 6.8$ billion yen $+ 34.5$ billion yen

Finally, let us estimate the annual costs that are inflicted on public medical insurance when official documents on notification of 'injury and sickness by a third party act' are not submitted. Unfortunately, no data on the rate of unreported documents is available, but according to Japan Medical Association data (2012), the proportion

Table 1   Overview of the two systems of public insurance in Japan

	Compulsory Car Insurance System (*Jibaiseki-hoken*)	Public Medical Insurance System
Source of revenue	Premium	Premium Tax Out-of-pocket payments by patients
Annual revenue	805 billion JPY (FY 2011)	42 trillion JPY (FY 2013)
Insurers	Private non-life insurance companies (including *Kyosai**)	Legal public insurers
The Insured	Car owners (based on each vehicle)	Residents/employees and their dependents
Insurance benefits	By cash (often by service in reality)	By service
Prices of medical services	Determined by hospitals and clinics, not the government	Determined by the government

*Kyosai is considered to be a scheme, formed by residents in the same region or persons engaged in the same occupation, which provides a certain amount of benefits from the pooled financial contributions of the members in the case of disaster, death or accident (Financial Services Agency website: http://www.fsa.go.jp/en/refer/ins/kyosai.html).[7] It differs from other private insurance companies in that it is a not-for-profit organization.

of medical institutions that do not make casualties aware of the need to submit these documents is 28.6%.[5] Assuming that this rate is equivalent to the rate of unreported documents, the annual costs that are inflicted on public medical insurance can be estimated to be approximately 11.8 billion yen. Importantly, these costs should in principle be covered by public and private car insurance.

The estimated costs are not large compared with annual total medical expenditure in Japan. They should, however, be compared to the finances of individual health insurance organizations, because many of these organizations have recently suffered deficits due to the recent sharp increase in medical expenditure. The costs —approximately 11.8 billion yen—are equivalent to the annual management costs of the largest health insurance association (Japan Health Insurance Association). This implies that eliminating these costs could save the annual management costs of Japan's largest health insurance association; and that is why these costs cannot be ignored.

History of the two systems of public insurance

The two systems of public insurance to cover the medical expenses of casualties of car accidents were enacted and executed in Japan in the early 1960s. The compulsory car insurance system (*Jibaiseki-hoken*) has been fully provided since 1955 and the public medical insurance system has been fully provided since 1961 by individual laws.*[2] **Table 1** provides an overview of the two public systems in Japan.

Soon after the two public insurance systems were established, a problem arose. Which system should be applied for covering the medical expenses of casualties of car accidents? In some cases, hospitals and clinics explained to patients that public medical insurance could not be used for casualties of car accidents. However, the government legally accepts individual choices between the two systems.

On October 12, 1968, the Ministry of Health and Welfare (MHW) issued an administrative notice stating that public medical insurance could be utilized for casualties of car accidents. This poses two implications: (i) The Health Insurance Act stipulates that legal public insurers of

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*2 Ikegami et al. (2011) describes the institutional framework and the history of public medical insurance in Japan.[6]

public medical insurance can claim for the expenses of medical services caused by a third party act against private insurance companies managing the financial affairs of compulsory car insurance; and (ii) The Health Insurance Act implies that the Japanese government allows individual choices between the two systems. If casualties choose to use public medical insurance, the insurer of public medical insurance covers the medical expenses temporarily and then claims for the expenses against private insurance companies.

In response to the MHW administrative notice, in 1969 the Japan Medical Association (JMA) publicly announced that public car insurance should be used in principle. The JMA provided two reasons for this. First, medical care for the casualties of car accidents should be categorized as disaster medicine. Medical care for casualties of car accidents is different from general medical care covered by public medical insurance because it is a form of disaster medicine. Second, the legislative intent of the compulsory car insurance system should be respected. The first priority of the system is to save casualties of car accidents. Therefore, compulsory car insurance and other private car insurance should be applied to cover the medical expenses of casualties of car accidents without the temporary use of public medical insurance (Japan Medical Association 1969).[8]

The issues regarding the two systems have historically been controversial. On August 9, 2011, the Ministry of Health Labour and Welfare (MHLW) issued another administrative notice, which stated that public medical insurance could be used for illness and injuries caused by crimes and car accidents. This implies that the government officially accepts individual choices between the two systems. In contrast, the JMA has consistently insisted that public car insurance should be prioritized in principle. In response to the administrative notice, the JMA broadly communicated its own stance to local medical associations.

Differences in the prices of medical services between the two systems of public insurance

In addition to the historical controversy described in the previous section, the difference in the prices of medical services between the two public systems further complicates the problem.

If public medical insurance is used, the prices of medical services are publicly stipulated in advance. In contrast, in the case of compulsory car insurance, the prices are flexible depending on hospitals and clinics; prices are usually higher for the latter.

In the 1980s, the prices of medical services when using compulsory car insurance provoked a social problem. In 1984, the Committee of Compulsory Car Insurance, an advisory body to the Minister of Finance, pointed out that the amount claimed for medical services against compulsory car insurance by some hospitals and clinics was extremely high. The committee also recommended that the stakeholders (the JMA, the industry group of private non-life insurance companies, and the General Insurance Rating Organization in Japan (GIROJ)) should provide a standard price list for medical services under compulsory car insurance.

In response to the recommendation, the JMA, the industry group of private non-life insurance companies, and the GIROJ cooperated in creating a standard price list and presented this list to the committee in 1989. The JMA and the other stakeholders have attempted to promote the list, because the price list has no legally binding force. As of 2013, 46 out of 47 local medical associations in Japan have officially accepted the list, and approximately 70% of hospitals and clinics have adopted it. The prices of medical services on the list are approximately 44% higher than those stipulated by the government when using public medical insurance.

Results of International Survey Analysis

This section explains the main findings of an international survey conducted by the authors. **Table 2** shows an overview of the survey. The objective of the survey was to understand the institutional design of public insurance systems for covering the medical expenses of casualties of car accidents in major countries. Questionnaires were sent to 19 countries by e-mail and fax on July 4, 2013, and responses were received from 12 countries by September 30, 2013.

Is car insurance compulsory?

Table 3 shows whether or not the 13 countries have compulsory car insurance systems. Almost

Table 2   Overview of the international survey

Objective	To comprehend the institutional design of public insurance systems for covering the medical expenses of casualties of car accidents in major countries.
Subjects	19 countries (Australia, Brunei, Canada, China, France, Germany, India, Indonesia, Italy, Korea, Malaysia, New Zealand, Philippines, Singapore, Taiwan, Thailand, U.K., U.S., and Vietnam)
	Responses were received from 12 countries (Canada, China, France, Germany, Italy, Korea, Malaysia, Philippines, Taiwan, Thailand, U.K., and U.S.)
Method	Questionnaire (Questionnaires were sent to medical associations or government agencies in the 19 countries by e-mail and fax on July 4, 2013, and responses received from 12 countries by September 30, 2013.)

Table 3   Is there compulsory car insurance in your country?

	Yes	No	Notes
Japan	○		
Canada	○		
China	○		
France	○		
Germany	○		
Italy	○		
Korea	○		
Malaysia	○		
Philippines	○		
Taiwan	○		
Thailand	○		
U.K.	○		
U.S.	△		There is no compulsory car insurance only in the state of New Hampshire.

all of the countries (except the state of New Hampshire in the United States) have compulsory car insurance systems. It is possible to say that compulsory car insurance systems are universal systems for motorized societies.

Who manages the financial affairs of compulsory car insurance?

Table 4 shows who manages the financial affairs of compulsory car insurance in the 13 countries. Governments are responsible for the financial management of compulsory car insurance in Thailand and Malaysia, whereas private insurance companies are responsible in Japan, Canada, France, Germany, Italy, Korea, the Philippines, Taiwan, and the United Kingdom. Private insurance companies and state-owned companies manage the financial affairs of compulsory car insurance in China. In the United States, it depends on the state. Japan is not unique with regard to private insurance companies managing the financial affairs of compulsory car insurance. Managing the financial affairs of compulsory car insurance through private companies might be an efficient method in advanced countries that have highly developed insurance industries.

Table 4 Agents who manage the financial affairs of compulsory car insurance

	Governments	Private insurance companies	Others	Notes
Japan		○		
Canada		○		
China		○	○	State-owned insurance companies also manage financial resources.
France		○		
Germany		○		
Italy		○		
Korea		○		
Malaysia	○			
Philippines		○		
Taiwan		○		
Thailand	○			
U.K.		○		
U.S.	○	○		

Table 5 Fault for casualties in car accidents

	Reduced by the fault for casualties	Reduced only when the rating blame of casualties is higher than the specified criterion	Not reduced	Notes
Japan		○		
Canada			○	
China	○			
France			○	
Germany		○		
Italy	○			
Korea			○	
Malaysia	○			
Philippines			○	
Taiwan			○	
Thailand		○		
U.K.			○	
U.S.	—	—	—	It is complicated and depends on the case under consideration.

Fault of casualties in car accidents

Table 5 shows how the fault for casualties in car accidents is handled in the 13 countries. In China, Italy, and Malaysia, the amount of compensation is reduced by the extent of the fault for the casualties. In Japan, Germany, and Thailand, the amount of compensation is reduced only when the extent of the fault for casualties is higher than the specified criterion. The amount of compensation is not reduced in Canada, France,

Table 6   Relationship between the two systems of public insurance

	Compulsory car insurance	Public medical insurance	Either compulsory car insurance or public medical insurance can be used	Both compulsory car insurance and public medical insurance can be used	Other	Notes
Japan			○			
Canada				○		Acute care treatment is provided by public insurance, and rehabilitation and long-term care tends to be provided by car insurance.
China	○				○	There is Social Salvation Fund in Road Traffic Accident.
France	○					
Germany	○					
Italy	○					
Korea	○					
Malaysia	—	—	—	—	—	Unclear.
Philippines				○		Either of the two public insurance systems is adapted to specific cases. Details are not clear.
Taiwan				○		Either of the two public insurance systems is adapted to specific cases. Details are not clear.
Thailand				○		Public medical insurance is used if the medical expenses exceed the compulsory insured limit.
U.K.		○				
U.S.				○		If you are eligible under Medicaid/Medicare that is used first and supplemental private insurance is used second, and if you are not eligible under Medicaid/Medicare, private car insurance is applied.

Korea, Taiwan, the Philippines, or the United Kingdom. In the United States, it depends on the case under consideration. The way of dealing with the fault for casualties differs among the respondent countries, but countries that do not consider fault for casualties in the compensation of medical expenses are in the majority. It may be appropriate that in Japan the fault for casualties should not be considered in the compensation of medical expenses in public insurance.

Relationship between the two systems of public insurance

Table 6 shows the relationship between the two systems of public insurance in the 13 countries.

In Japan, it is possible to choose either compulsory car insurance or public medical insurance. In China, France, Germany, Italy, and Korea, only compulsory car insurance can be used. China has the Social Salvation Fund in Road Traffic Accident. In the United Kingdom, only public medical insurance can be used. In Canada, the Philippines Taiwan, and Thailand, both systems can be used, with either of the two public insurance systems being adapted to specific cases. As the United States has no universal health insurance coverage, the system is complicated: if you are eligible under the Medicaid/Medicare systems, they are used first and supplemental private insurance is used second; if you are not

Table 7 Differences in prices of medical services

	Exactly the same	The price in the case of using compulsory car insurance is higher	The price in the case of using public medical insurance is higher	There are differences in price. Which is higher depends on the kind of medical service	Other	Notes
Japan		○				
Canada		○				
China	○					
France	○					
Germany	○					
Italy	○					Compulsory car insurance covers all cases.
Korea					○	The prices between the two public insurance systems are equal in clinics, but the price in hospitals is higher in the case of using compulsory car insurance.
Malaysia	○					It is conceivable that compulsory car insurance covers all cases.
Philippines	—	—	—	—	—	Difficult to answer.
Taiwan		○				
Thailand	○					
U.K.	○					NHS covers all cases.
U.S.	○					

eligible under Medicaid or Medicare, private car insurance is applied. Relationships between the two public insurance systems depend on the country, but Japan is quite unique in that people can choose between the two systems of public insurance.

Differences in the prices of medical services

Table 7 shows the differences in price for the same medical services between the two systems of public insurance in the 13 countries. The prices are exactly the same in China, France, Germany, Italy, Malaysia, Thailand, the United States, and the United Kingdom. The price in the case of public car insurance is higher in Japan, Canada, and Taiwan. Korea has a complicated pricing system: the prices under the two public insurance systems are equal at clinics, but the prices at hospitals are higher when compulsory car insurance is used. In addition to Japan, there are several countries—Canada, Taiwan, and Korea—where there are differences in price for the same medical services between the two sys-

tems of public insurance. Japan is not necessarily unique in the world in this respect.

Discussion

Interpretation of the results of the international survey

Let us summarize the results of the international survey. First, almost all countries have a compulsory car insurance system. Second, most advanced countries entrust private insurance companies with managing the financial affairs of compulsory car insurance. Third, the way of handling fault for casualties differs among countries, but the majority of countries do not consider fault for casualties in the compensation of medical expenses. Fourth, Japan is unique in that people can choose between the two systems of public insurance. Fifth, in addition to Japan, there are several other countries where prices for the same medical services differ between the two systems of public insurance. Japan is not necessarily unique in the world in this respect.

To begin with, it is incontrovertible that private insurance companies manage the financial affairs of compulsory car insurance. Apart from this point, it is possible to formulate options. It may not be necessary to consider fault for casualties in the compensation of medical costs in the case of car accidents. Next, being able to choose between the two systems of public insurance in the case of car accidents may not be a good idea. Furthermore, there is an alternative for equalizing the prices of medical services between the two systems of public insurance. Five specific options are discussed after the next section.

Essential issues that should be resolved

Three essential issues that should be resolved were detected. First, different prices under the two systems of public insurance provide stakeholders with irrelevant incentives to choose public medical insurance in the case of car accidents, although public and private car insurance should be applied in principle. Prices under public medical insurance are lower than those under public car insurance. Therefore, those responsible for paying medical expenses have the incentive to apply public medical insurance rather than public car insurance. In this case, private insurance companies and individuals at fault have the rational but inappropriate economic incentive to apply public medical insurance in the case of car accidents. If the current system under which people can flexibly choose between the two systems of insurance is maintained, the prices between the two systems of insurance should be equalized in order to avoid providing irrelevant incentives.

Second, medical insurance ends up covering irrelevant medical expenses if official documents of notification of 'injury and sickness by a third party act' are not submitted. Casualties are legally required to submit official documents of 'injury and sickness by a third party act,' but it is difficult to ensure that they do so simply because they are victims of car accidents and are suffering from injuries. Under the current situation, not all cases are appropriately reported. In the end, public medical insurance incurs the costs of medical services provided to casualties of car accidents, although public and private car insurance should cover these costs in principle. Hence, the expenses that public medical insur-

ance initially covers should be automatically reimbursed by public and private car insurance when public medical insurance is applied first in the case of car accidents.

Third, the party who ultimately covers medical expenses differs between the two systems of public insurance because the financial contributors to each system are essentially different. The financing of public medical insurance comes from insurance fees and taxes, while the financing of pubic car insurance comes only from insurance fees. If public medical insurance is used, the costs are inflicted onto tax payers in addition to insurers in public medical insurance, not onto insurers in public and private car insurance. It is an unfair situation that imposes these costs on tax payers without their realization.

Options for resolving the conflicts

Based on the essential three problems that need to be solved, this paper provides five options for the resolution of these conflicts. The first option is simple: forbid the use of public medical insurance in the case of car accidents. When car accidents happen and people need to cover the medical expenses of casualties, public and private car insurance should be applied from the beginning. In this case, different prices between public medical insurance and public car insurance do not matter because public medical insurance cannot be used for car accidents. The irrelevant economic incentive to apply public medical insurance to car accidents disappears in this option. You should be only concerned with the problem of asymmetric information between medical service providers (hospitals and clinics) and demanders (payers), because prices can be flexibly set by individual hospitals and clinics when car insurance is applied. Car accidents are emergencies; thus, casualties have no time to lose in obtaining information on prices. Fault-offsetting may impose unexpectedly large costs on casualties. In addition, if public medical insurance can never be utilized in the case of car accidents without exception, casualties will suffer from lasting medical costs after public and private car insurance ceases to cover them. Public medical insurance should be applied after the application of car insurance has ended. However, insurance companies would still have the irrelevant economic incentive to terminate the application of car insurance as soon as possible.

Under the second option, public medical insurance is always applied, even in the case of car accidents. However, car insurance should cover medical expenses in principle. Thus, the costs that public medical insurance covers should be completely reimbursed by car insurance. Casualties submit claims to insurance companies for the costs that they pay as out-of-pocket expenses. Public medical insurance associations submit claims to insurance companies for the costs that they cover without the submission of notification of 'injury and sickness by a third party act.' Under this option, prices should be public prices provided by the government under the public medical insurance system.

The third option is based on the current system. The only difference is placing premiums on public fixed prices under the public medical insurance system when medical expenses are reimbursed by private insurance companies. Basically, the reimbursement is executed only after notification documents on 'injury and sickness by a third party act' are submitted by casualties. Under this system, not all the reimbursements may be made. Therefore, premiums should be provided in order to deal with such risks for public medical insurance. Premium prices should be determined according to real data on risks.

Under the fourth option, prices of medical services under public medical insurance and car insurance are made exactly the same. If prices are the same, no stakeholder has the inappropriate economic incentive to prioritize public medical insurance under any circumstances. However, in this case, there is still the risk that notification documents on 'injury and sickness by a third party act' will not be reported by casualties. We may need to combine the second or third option with this fourth option in order to counteract this risk. Furthermore, we must also consider political issues, because the prices for medical services in the case of car accidents are made lower for political reasons—a situation that may be repulsive from the viewpoint of medical service providers.

The final option is that car insurance does not cover medical expenses for casualties. Instead, car insurance focuses on the payment of consolation money, leave compensation, and compensation for residual disability. Under this option, public medical insurance needs to cover medical costs for casualties. Therefore, the insurance fees for car insurance should be lower than the current level. Alternatively, systems for transferring funds from car insurance to public medical insurance in advance are required.

Selection from among the five options above should be politically determined. However, the third option seems most realistic, considering the current status of the systems. It may be possible to adopt the third option more easily.

Limitations of international comparisons

A questionnaire survey is not necessarily the best way to consider an ideal system. The purpose of an international survey is to internationally compare and realize implications for considering the research issues. It is hard to identify directly which is the best system on the basis of international survey analysis. Fundamental considerations of what is the best system in the context of each country are required.

In particular, the issue that this paper mainly discusses is unique and specific to Japan, because it is only in Japan that it is possible to choose between the two systems of insurance in the case of car accidents. Consequently, respondents in each country seemed not to have completely understood this main issue when they filled out the questionnaire. We therefore need to interpret their answers carefully and add notes in some cases.

Conclusion

This paper clarifies essential issues concerning conflicts between public car insurance and public medical insurance in Japan, presents the findings of an international survey to detect similar problems in other countries, and discusses possible options for resolving these conflicts.

Three essential issues were identified. First, applying prices under the two systems of public insurance provides stakeholders with irrelevant incentives to choose public medical insurance in the case of car accidents, even though public and private car insurance should be applied. Second, medical insurance incurs irrelevant medical expenses when notification of 'injury and sickness by a third party act' is not submitted. Third, if we use public medical insurance, the costs are imposed on tax payers unconsciously; it is unfair.

Five findings were obtained from the international survey. First, almost all countries have a compulsory car insurance system. Second, private insurance companies manage the financial affairs of compulsory car insurance in most developed countries. Third, the fault for casualties is not considered in the compensation of medical expenses in most countries. Fourth, Japan is unique in that people can choose between the two systems of public insurance. Fifth, there are several countries in which prices for the same medical services differ between the two systems of public insurance.

This paper provides five options for resolving the conflicts between public car insurance and public medical insurance in Japan. First, the application of public medical insurance in the case of car accidents is prohibited. Second, conversely, public medical insurance to car accidents is always applied. Third, premium prices on medical services provided under public medical insurance are set when the medical costs are reimbursed by private insurance companies, based on the current system. Fourth, the prices of medical services between the two systems of public insurance are equalized. Finally, medical expenses for care accident casualties are never covered with car insurance; instead, car insurance covers the payment of consolation money, leave compensation, and compensation for residual disability. The five options above would contribute to the solution of the issues. The third option seems most feasible, considering the current conditions.

Focus should be placed on victims' compensation because the risks of car accidents are intrinsically prevalent in motorized societies. From this perspective, further discussions are required to improve the insurance systems.

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A Report on the Junior Doctors Network (JDN) Meeting: The JDN's Challenges and Future Prospects

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Introduction

We would like to report on the Junior Doctors Network (JDN) Meeting held in conjunction with the 2013 World Medical Association (WMA) General Assembly in Fortaleza, which we were given the opportunity to attend as practitioners representing junior doctors in Japan. The meeting preceded the opening of the WMA meeting and took place on the 14th and 15th of October in Fortaleza, the capital of Ceará, a northeast state of Brazil.

JDN History

Approved at the WMA conference in October 2010, the JDN is the world's first international platform for young medical practitioners around the world. The goal of the JDN is to provide a forum for experience-sharing, policy discussion, and project/resource development on issues of interest to junior doctors, including (but not limited to) global health, postgraduate training, safe working conditions, and physician migration. The new organization presently has members in about 50 countries. In Japan, the domestic version of the JDN was launched in 2013, initiated by young doctors and the members of the Medical Student Subcommittee of the Japan Medical Association (JMA). The group has just recently become active, with 21 young Japanese doctors registered as members. In 2013, one of the member doctors attended the WMA General Assembly in Indonesia in April, and another member took part in the Confederation of Medical Associations in Asia and Oceania (CMAAO) meeting held in India.

JDN Meeting Report

For the JDN's two-day meeting in Fortaleza, 21 members from 11 countries, including Japan, joined the activities. On the first day, representatives from participating countries introduced their current JDN activities and issues they are facing. In this meeting, members from Canada, Jamaica, Korea, Turkey, Germany, Brazil, and France made presentations and shared their experiences. Except for Turkey, which established their JDN as an entirely new organization, all participants were representatives of existing groups for young doctors. One presentation which impressed us greatly was the one by Canada, which also has the Canadian Association of Interns and Residents (CAIR), an organization representing about 8,000 residents nationwide. This group is engaged in activities such as medical education and policy/advocacy, as well as physicians' well-being, and has already implemented a large number of projects. At the time of the presentation, the organization was carrying out the Annual Survey of Canadian Residents, a questionnaire survey evaluating practitioners' well-being in terms of various aspects, such as working hours and working environments, mentorship, career counseling, and employment opportunities. We found their activities and organization particularly inspiring

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as a guiding reference for our future activities in Japan. The participants then went through a review of WMA policy then presented their member country's respective statements and discussed them. Among the topics concerning human sexuality, a policy statement asserting that homosexuality is not a disease but within the scope of nature (normality) attracted an extremely lively debate. The depth of social, cultural and religious differences among the participating countries, some of which legally prohibit homosexuality, left a strong impression.

The participants were then briefed on current JDN activities regarding the "Well-being Policy White Paper," "Global Health and Ethical Implications," "Global Survey: Postgraduate Medical Education," and "Workforce Policy Paper," as well as the JDN's participation at various international conferences. In particular, a Working Group on Patients' Well-being has been established within the JDN; this working group has been very active and formulated a policy statement. This policy proposal was approved by the WMA General Assembly, and it was decided to carry on the discussion within the framework of the WMA. Also, during this session, the Japanese and Korean JDNs took the initiative in proposing that a JDN meeting be held in conjunction with the WMA Mid-term Council Meeting to be held in Tokyo in April 2014, which was approved by the Assembly.

JDN Election Term for 2013/2014

On the second day of the JDN meeting, executive members of the JDN were elected. Prior to this event, the organization announced the election and called for candidates through the JDN mail magazine, and the candidates' profiles, (including Motivation Letters and CVs), were shared online. As some candidates were unable to attend the meeting in Brazil, the organizer arranged an online system through which participants could ask the candidates questions. This time, Korean and Myanmar representatives were elected from the Asian region, promising further involvement of the region in JDN activities.

The JDN's Challenges and Future Prospects

Exchanges during the JDN meeting suggested that young doctors across the globe share largely the same problems, such as working hours and labor environments. In this sense, it seems very beneficial for junior doctors to step beyond the boundaries of their specialties to work and voice their opinions together on the JDN platform. At the same time, however, the organization has issues in terms of its operational structure. The group is still young and therefore is immaturely structured, with no clear divisions between different roles. This makes it difficult for the organization to coordinate its activities with outside establishments. Future JDN meetings will focus on the importance of the meeting itself.

As for the JMA-JDN (Japan Medical Association-Junior Doctors Network), the group is currently working on three core activities: establishment of a structured affiliation between the organization and the JMA; promotion of JDN visibility; and implementation of Annual Survey targeting junior doctors. Through its Annual Survey, the group aims to identify the concerns and preferences of young doctors in Japan regarding their work, living, and study environments and make policy proposals based on these findings as the consensus of the young generation. JDN has members across the country, and these members are in regular contact through online and actual face-to-face meetings to discuss these issues.

With regard to the JDN meeting in Tokyo scheduled for April, as the host of event, the JMA-JDN is committing itself to making the meeting an opportunity for the JMA-JDN to establish close ties with Asian countries and strengthen the network between Asia and the world. Through this event, we expect that more young practitioners in Japan and Asia will involve themselves in JDN activities, identify common problems and concerns shared among them, and voice these issues within the international community in order to promote the presence of the organization. Although the history of the JDN has only just started, its activities have great potential to connect young doctors across the world. Through policy making, learning about other countries' medical systems and practices, and researching and studying abroad within the new framework, the future JDN will be able to provide young doctors with a new platform of learning. As for the JDN-JMA, it will expand its activities as one of the few organizations representing junior doctors in Japan.

Conclusion

At the WMA General Assembly held after the JDN Meeting, we had the opportunity to closely observe the historic decision following discussions on the revision of the Helsinki Declaration. It was highly educational to watch prominent doctors from around the world exchanging opinions backed by solid visions and to witness the roles and significance of national medical associations. We would like to make the best use of this precious experience to enhance the activities of the JMA-JDN. Last but not least, we would like to express our heartfelt thanks to the WMA and JMA for giving us such a precious opportunity.

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From the Editor's Desk

In a recent trend, there has been an increasingly strong demand for the utilization of advanced computer technology in combination with technological innovations in the medical field; the setting-up of big medical and/or health databases with broad applications, including in the commercial field; the establishment of bio-banks based on unique information and/or materials to meet a wide range of needs, from general medical needs to quite individualistic desires. Such energy for creating new categories cannot be absorbed into one specific current category, such as traditional law or bioethics.

We therefore wish to overwrite the WMA Declaration database in light of the total overhaul of the Declaration of Helsinki as an ethical guideline for physicians in dealing with human subjects that was accomplished by the new WMA Working Group in Fortaleza in 2013.

The JMA's activities in the same field were fruitful in creating an international symposium on big data and databases within the JMA Conference on Medical Information 2014, which was held in February. The symposium welcomed three international guests: Dr. Jon Snædel, Chair of the WMA WG and Past President of the Icelandic Medical Association; Dr. Robert Wah, President-elect of the American Medical Association; and Dr. Don-Chun Shin of the Korean Medical Association. I was honored to give the opening address and co-chair the session.

The results of this fruitful meeting will directly connect with the Working Group (WG) meetings which was held in Reykjavik and Copenhagen to create the newest version of the WMA Declaration as the current guideline in this field.

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Principles of Medical Ethics

Japan Medical Association

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

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

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

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

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

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

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