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Scientific Contribution

The Disclosure of Medical Records to Patients
－The Japanese Experience－

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Abstract :

Do patients have free access to the medical records of their own stored in the medical institutions where they receive examinations or therapies? In Japan until around 2000, the law was silent about the patients' general legal right to see their own medical records, and they could obtain copies of the records only when the court declares that medical institutions may destroy the evidence and thus issues a court order to secure copies of the original records. This paper traces a series of events concerning this matter in the period from 1990 to 2004, when the Personal Information Protection Law had been approved by the Diet and the preparations had started in the field of medicine. What emerged in the process were different approaches to medicine: the Japan Medical Association wanted to maintain physicians' autonomy and to retain therapeutic privileges if necessary, while the outside world took for granted peoples' general right to know information concerning themselves and thought of clinical information as no exception. This difference led to the debate whether to stipulate patients' legal right to have access to their medical records or not.

Keywords : Informed Consent, Access to Medical Claims, Access to Medical Records, Personal Information Protection Law, Physicians' Autonomy

The idea of informed consent in medical settings was

introduced to the medical world and also to the general public in Japan around 1980 by several Japanese scholars familiar with changes in the United States. In the legal area, on the other hand, after several lower courts' rulings, the Supreme Court in 1981 confirmed the duty of physicians to disclose to patients information concerning planned medical interventions. With the increasing emphasis on informed consent and also in the ongoing questionings of what the idea means, one topic which emerged was whether medical institutions should show, or give copies of, medical records in their hands to patients at their request. The law said only that physicians have to keep each patient's medical records up to date, and many medical providers assumed that medical records are their own property. This paper traces a series of events concerning the disclosure of medical records during an approximately fifteen-year period from 1990.

Ⅰ. Background, 1990 – 1993

In 1990, the Japan Medical Association's Bioethics Council issued a report on "Explanation and Consent." [1] This report notes that due to cultural differences between the West and Japan, it is not quite appropriate to introduce directly the Western version of informed consent in Japanese settings. On the other hand, however, physicians' explanations and patients' consents are said to be very important, since they help to build the trust relationships between these two parties and also they make therapies more effective, since the patients tend to be more cooperative once they have been informed enough.

In 1992, when the Diet deliberated on a revision of the Medical Service Law, one member asked to insert the informed consent clause in the law itself. In the end, the law went only as far as to say that medical providers should make efforts to offer appropriate information and to help patients understand the

information. But in one of its supplementary provisions, the government was obliged to work on possible measures, so that medical providers effectively offer appropriate information to patients.

In 1993, the Ministry of Health and Welfare, following the above provision in the revised Medical Service Law, set up a committee to explore how to implement the idea of informed consent in medical practices. Among its fifteen members, nine were from the medical field, four from the general public, and two from civil law. Its chairperson was a well-known non-fiction writer, Mr. Yanagida (hereafter the Yanagida Committee of 1993). In 1995, it issued a report, with the subtitle, "Informed Consent Which Will Raise Your Spirits." [2] The subtitle was meant to erase fears and to minimize reluctances on the part of medical providers surrounding informed consent, since several court cases warned that the lack of obtaining the informed consent from patients would lead to legal liability, and further the time and efforts needed for the informed consent rituals seemed nothing but a waste for many professionals. Instead, the report claimed, the idea of informed consent is supposed to make possible new and better relationships between patients and medical professionals: patients who want to be informed of their conditions and medical providers who are aware of the importance to patients of medical information could start a cooperative undertaking to overcome medical problems, and thus medical providers could bring their professional knowledge and skills into full play.

The phrase "possible measures" in the above provision of the Medical Service Law suggested to some members of the Yanagida Committee that the idea of informed consent should be incorporated in the Medical Service Law in one form or another, and this became a topic in this committee's meetings. The report touches on this issue.

First, it discusses the proposal of making it a legal duty. It is true that informed consent contributes to promotion of the trust relationships between patients and medical providers, and also some court rulings require physicians to disclose enough information to patients. But, the relationships in medical encounters are between individuals, and therefore each case is different from others and requires unique and individual attention, while the law aims to cover all diverse cases in simple phrases, abstracting from specific nuances. When enforced by law, informed consent procedures may become perfunctory and only ceremonial simply to avoid legal liabilities. Therefore this proposal is not acceptable.

Second, some members proposed to incorporate the idea of informed consent into the Medical Service Law as a goal to strive for. On this, some contended that informed consent practices could be promoted only by the conscious efforts of patients and medical providers, not by stipulating it in a legal provision. On this point the committee could not reach a conclusion, and hoped that further discussions would be held.

Ⅱ. The disclosure of medical claims, 1993 – 1997

After each visit at a clinic or a hospital, patients pay their share of copayments and the rest is covered by the insurance groups they belong to. To collect the remaining remunerations, each medical institution produces an itemized statement of medical expenses, called a medical claim, at the end of each month, one for each patient. Those claims are first sent to the associations of health insurance groups, and the associations, after review, in turn sort and send them to each health insurance group. The law was silent about whether the patient can have access to the claims, but the Ministry of Health and Welfare had issued an administrative guidance which forbade their disclosure

to patients. [3] The reason the Ministry cited was that the diagnosis written in the claim sheet might have unfavorable therapeutic effects.

Several factors contributed to the change in the attitude of the Ministry and eventually the Ministry asked each health insurance group to comply with the request from the patient to have access to the claims in its hands.

One of the factors was the fraudulent overcharging of expenses by medical institutions by writing in the claims items of medical interventions not performed. The health insurance associations were to check the claims but could go only as far as to see whether the interventions match the diagnosis. If in a claim a medical institution write in another diagnosis and a treatment for it in addition to the actually offered treatments, there was no way to discover these kinds of illegal claims, since the patient, the only possible witness about the treatments, was denied access to the claim sheets, or the health insurance body could not ask the patients if they really received this or that treatment written in the claims. Major newspapers from time to time ran series of articles on this issue, though most witnesses of those frauds were anonymous. The readers' reactions to those articles suggested that the fraudulent overcharging was far more widespread than was reported. [4]

The developments of medical technology and the advent of the ageing of Japanese society caused medical expenditures to rise sharply year by year. Consequently, financial burdens on the people increased, particularly as the rise of copayments ratios and as the increasing contributions of health insurance groups to medical expenditures for the older people. In a broader perspective, it may be necessary to take measures, such as raising patients' copayments, but at a micro level, the media and the general public expressed dissatisfaction to the reform proposals, since there were frauds which take advantage of the

system. They asked the government to uncover and correct them as the first indispensable step of reforms.

The second factor is the lesson from the HIV infection of hemophiliacs. Japan used to make blood products for hemophiliacs using the blood donated by Japanese people and also the blood imported from the United States. Some of the imported blood contained HIV, and thus the blood products became contaminated with the virus. In the mid 1980's many hemophiliacs contracted HIV, and some patients died due to the infection and AIDS complications. In 1984 it was found that heating would inactivate the virus, and in 1985 the heated blood products became available to the patients. In the ensuing legal suits, both civil and criminal, one of the issues was whether the Ministry was swift enough to order the change from unheated to heated products, and more specifically when the Ministry became aware of the risk of HIV infection for hemophiliacs. The latter specific issue was supposed to uncover which patients became unnecessarily infected with the virus, due to the negligence of the Ministry.

In December 1995, the government issued an official statement on the hemophilic-HIV matter, and insisted that in 1983 the Ministry of Health and Welfare and its task force were not aware of the infection risks, and further that there were no files which show the awareness at that point. However, in February 1996, the Minister of Health and Welfare, Naoto Kan (who was later Prime Minister in 2011) announced that there were about 30 files in the Ministry's archives which suggested the risk information was shared among the bureaucrats in the drug section.[5] The Ministry, after strong criticisms from the public, decided on a new policy concerning drug administration, titled "On the measure to prevent health injuries arising from pharmaceutical products," and promised to be more open about the information it will obtain.

The third factor was citizens' movements for more extensive disclosure of medical information. Many of them were started by those who suffered from adverse events in medicine and suspected malpractice or cover-up, and therefore they also asked for the disclosure of official documents, such as medical records and claims. They built national networks and held various meetings. Their voices were not strong enough, but at the same time not so feeble to be ignored by policy makers.

The fourth factor is the lawsuits on alleged medical malpractices. Around 1990, many prefectures and big cities had enacted personal data ordinances, and they contained a provision that citizens can have access to information relating to themselves, as well as provisions to protect personal information generally. Once the lawsuits start, the plaintiffs could obtain copies of their medical records by court order as preservation of evidence. But often the plaintiffs were suspicious of the authenticity of the records, since the records were several years old at the time of the lawsuits, and wanted to see the claims which were submitted immediately after the treatments, so that they could compare the records with the claims. In a lawsuit which began in 1993 in Kyoto City, a couple asked the city to disclose the medical claims of their children, because they were members of the health insurance group run by the city, and the city had a personal data ordinance. The city was in a dilemma, since on one hand the medical claims were really personal data in the city's possession, and therefore its citizens could demand access to them, but on the other there was no explicit text in any law about their disclosure and further there was an administrative guidance from the Ministry of Health and Welfare not to disclose them. After several consultations with other offices, finally in 1995 the city handed the copies to the couple. [6] In 1996, Osaka City disclosed one patient's medical record in its prefectural hospital, following the personal data ordinance, not

by court order, and also the claims kept in its health insurance group archives.

The final step was a decision by a higher court. In 1993, a couple in Hyogo Prefecture, whose baby had died shortly after its birth, filed a civil lawsuit against the clinic. They wanted to have a copy of the claims at the time of the baby's birth, in addition to the copy of the medical records already obtained through a court order. The prefectural office, which kept the claims, declined the request, and the couple filed another lawsuit for the prefecture to disclose claims. The lower court ruled against the plaintiffs, saying there are no clear provisions in the prefectural ordinances to disclose the claims. The couple appealed to the higher court, and this court supported the couple's request, saying in principle the public documents should be disclosed, as long as there is no fear of privacy infringement, and more specifically in this case, the documents in question contain only the personal data of the people concerned. [7]

Pushed by this ruling, in June 1997, the Ministry of Health and Welfare reversed its position and asked health insurance groups to disclose the medical claims in their hands to their members when requested. The Ministry added two points to note: first, to contact the clinic or hospital which produced the claims in order to make sure the disclosure will not have any therapeutic undesirable effects, and second, to be flexible and understanding when the family members of a deceased patient want the disclosure. As of March 1988, nine months after the new measure was introduced, most health insurance groups already started, or were ready, to disclose the claims and nationally more than 4,000 claims were disclosed. [8]

Ⅲ. The Committee on the Utilization of Clinical Information, Such As Medical Records (the Morishima Committee of 1997), 1997 – 1998

In 1997, the Ministry of Health and Welfare set up The Committee on the Utilization of Clinical Information, Such As Medical Records. Among the factors which prompted the setup of the committee was, firstly, the commitment of the Ministry, after the alleged hemophilia-HIV mismanagement, to explore ways to inform patients as well as the general public of medical information more extensively, such as the disclosure of medical records to patients. Secondly, when the Medical Service Law was revised in 1997, the clause was added that medical providers should try to offer appropriate explanations and help patients understand them (this was a point left unresolved in the Yanagida Committee of 1993, but eventually the bill was drafted by the Ministry and approved by the Diet). This committee had thirteen members, seven from the medical world, four from the legal world, and two as representatives of the general public. Its chairperson was Mr. Morishima, a civil law professor at Nagoya University and also formerly a member of the Yanagida Committee of 1993.

The committee issued its final report in June 1998.[9] The chairperson's being a law professor seems to have had significant effects on the content of the report. First, the fourth chapter mentions two reasons why the disclosure of clinical information is necessary: (1) to build strong trust relationships between medical providers and patients and also to improve the quality of medical practice by sharing the information, and (2) for the patients to have self-control over the information about themselves. The first reason was often referred to in the documents concerning informed consent, and was gaining support in the medical world in Japan at the time. This was also the Yanagida Committee's basic stance. The second reason must have been discussed in various committees, but as the majority of members were from medicine, it had never been mentioned in

their reports. The conventional wisdom in the legal world and also among the general public finally made its ascent here in an official report on informed consent.

The second point to note is in the ninth chapter titled "Proposal for legislation." The committee's conclusion was that a legal provision should be laid down which says that medical providers must disclose patients' medical records in their hands to the patients upon their request. It briefly summarizes the discussions leading to this conclusion during the committee's meetings. On one hand some members said that emphasis must be put on the patients' right to know and on the way to give redress to the victims of medical malpractice, and therefore their rights to have their own clinical information disclosed should be legally stipulated. On the other, some said that hasty legislation may cause confusions in medicine and hinder the pursuit of medicine's primary goal, i.e. the practice of good medicine. Yet, the committee's final position was that the creation of the legal right on the part of patients to have access to their own medical records and of the legal duty on the part of medical institutions to disclose to patients their own medical records should be pursued, since, firstly, the disclosure should be promoted and realized more extensively, and secondly, in society as a whole the idea of self-control of personal data is considered more and more important and various institutions have taken measures to put the idea into effect.

A newspaper report [10] describes how the committee discussed this issue. On April 23, 1998, a draft of the report was submitted by the secretariat office of the committee. It consisted of ten chapters, but the content of the ninth was in a separate sheet, titled 'Proposal for legislation,' prepared by the chairperson himself. The office thought the consensus that could be reached in the committee might go only as far as creating the guidelines to promote disclosure, yet Morishima was not happy with the

lukewarm direction and pushed for legislation. The office bureaucrats were apparently surprised by the uncompromising attitude of the chairperson. As was expected, there were many criticisms from the members in the medical world. The representative from the Japan Dental Association expressed displeasure, saying "We have to recall what happened after the disclosure of medical claims. There took place a movement to get back the overcharged medical fees. The legislation on medical records may be taken advantage of by malicious citizens." One hospital administrator commented that now the doctors fill in medical records for their own uses, not having in mind the possibility of showing them to patients, and therefore, before legislation the proper management system of medical records must be explored. At the end of the session, Morishima stated, "I did not expect these strong criticisms, but I do not plan to make concessions on the fundamental point and I will draft the final report in this vein."

The final report took into account the worries expressed by the medical members, while maintaining the basic legislation proposal. It proposed to take several preparatory measures before the legislation. Firstly, new positions should be created for the professionals who manage medical records comprehensively, like the Registered Record Administrator in the United States. They are expected to improve the quality of the records. Secondly, medical providers should be able to receive education on what to write in medical records and how to write them. Thirdly, further standardization of medical record writing and terminology used there is needed, since at present what the law requires to be written is only the patient's identity, the examination date, the symptoms, and the therapy offered, and therefore the contents are bound to vary from one professional to another. Before these measures are fulfilled to some extent, the summary of the offered therapies could be substituted for the disclosure of medical

records.

The Ministry of Health and Welfare sent this report to the Medical Council, the advisory body on medicine in general to the Minister, and in December 1998, the Ministry submitted a draft paper on the legislation to the Council. The paper's plan was that there would be a three-year preparatory period before the full enactment of the disclosure law. But the Council's discussions came to be greatly influenced by the Japan Medical Association's policy, which is the topic of the next section.

Ⅳ. The Japan Medical Association, Guidelines on the Disclosure of Clinical Information, 1998 – 2000

The representative of the Japan Medical Association in the Morishima Committee, Dr. Miyasaka, reported the outline of the Morishima committee's discussions and the JMA's standpoint to its members in JMA News.[11] Firstly, he emphasized that the JMA's policy on the promotion of clinical information disclosure prompted the creation of the committee. Secondly, he noted that there were many discussions on the legislation proposal and at the end they reached the conclusion that the step-by-step legislation must be preceded by the completion of several preparatory measures. And lastly, he makes clear the basic policy of the JMA: (1) the practice of medicine must be based on the trust relationships with patients, and (2) the JMA thinks clinical information must be, and actually is, disclosed to patients, and (3) it is opposed to the legislation of disclosure, since the disclosure must be made by physicians voluntarily, not by coercion, and therefore it is not amenable to legislation. He declares that the JMA as a professional organization is willing to extend the scope of disclosure more fully and to implement various preparatory measures for that purpose. More specifically, the JMA will set up a committee to draw up the guidelines on the

disclosure of clinical information in July 1998, one month after the report of the Morishima committee was made public.

This new committee had twelve members, eight from the medical world, one law professor, two lawyers who are advisors to the JMA, and one researcher in a JMA institute. After half a year's discussions, in January 1999, it made public the interim report, and after some revisions the report was approved by the board of delegates and its proposal became the JMA's official guidelines in April 1999. These guidelines were to come into effect in January 2000. [12]

The guidelines show some differences from the report of the Morishima committee, because of their being voluntary guidelines. First, the primary purpose is said to be overcoming patients' illnesses while maintaining the mutual trust relationships, and therefore the self-control aspect is deliberately left out. Second, the guidelines apply to daily medical encounters between patients and doctors, and further to cases where patients want to have second opinions, and, more importantly, do not apply where patients have lawsuits in mind. One possible reading of the lawsuit clause may be that as long as patients are not happy about the therapy and express loss or decrease of trust in one way or another, physicians can refuse disclosure, saying the trust relationship does not exist any more. Third, physicians can refuse disclosure more extensively than is usually accepted. It is widely agreed that exceptions of disclosure apply when self-harm or harm to others is foreseen. But the JMA guidelines added a third clause: when there is a grave enough reason to refuse disclosure. This may allow physicians to exercise their discretion more freely.

In 1999, The Medical Council deliberated the draft paper on the legislation prepared by the Ministry of Health and Welfare. By then, however, the outlines of the JMA guidelines were known to its members. There were two issues discussed in the Council

meetings: the legislation and patients' self-control over their medical records. [13]

About the first issue of legislation, according to the summaries of the meetings, there were pros and cons. Among the views opposed to the legislation were (1) the crucial point is the patients' choosing a course of therapy based on close communications with their doctors, and this could not be achieved by the letters of law, and the legislation should be considered as a last resort only when the guidelines turn out not to work, and (2) the JMA is asking various medical organizations to join in the more extensive disclosure efforts following its guidelines, and this is expected to be the policy of the whole medical world. On the other hand, some favored the legislation, saying (1) the JMA is a private organization and there are quite a number of non-member doctors, and hence its ethical guidelines will not be so effective, and (2) physicians' ethics has a long history, and it may be due to the self-righteousness of the doctors' world that the disclosure is now considered to be an ethical duty.

The second issue was whether to accept the idea of the patients' self-control over the information about themselves written in the medical records as a main reason for the disclosure, as was suggested in the Morishima report. Some pointed out that the right of self-control is so widely accepted in the outside world and the medical world should not be an exception, while others contended that medical records contain both the information of patients and the judgments of physicians, and therefore the outright disclosure of the records may amount to the infringement of the physicians' intellectual property.

The interim report adopted by the Council in July 1999 said that the more extensive disclosure should be pursued in order to build the trusting relationships between medical providers and patients, and also in order to make therapy more effective with the patients' more positive participation. On the legislation it

said only that opposing views were expressed and this issue should be explored still more. Kyodo [14] reported the dynamic process of deliberations in the Council in this way. At first many members leaned toward the idea of legislation without penalty. Yet the announcement of the JMA's guidelines changed the atmosphere drastically. The members from the JMA challenged other members, asking if they would not believe in the sincerity of physicians, when JMA was ready to disclose more extensively in the form of guidelines. The other members could not say that legislation was still necessary.

Thus the counterattack of the JMA on the legislation proposal succeeded. It became obvious that as long as the matter was discussed in the committees of the Ministry of Health and Welfare, there was no prospect of ascertaining the legal right for the disclosure of medical records. Yet one crucial reform in the outside world was to change the situation, i.e. the legislation of the Personal Information Protection Law in 2003.

Ⅴ. Preparatory Measures, 2000 – 2002

The 1999 interim report of the Medical Council also recommended that preparatory measures should be taken for more extensive information disclosure. In 2000, the Upper House suggested, when deliberating on the revisions of the Health Insurance Law and the Medical Service Law, that the government should pursue the legislation on the disclosure of medical records with due preparations. The Ministry of Health and Welfare (from 2001 on, the Ministry of Health, Labour, and Welfare, due to the restructuring of the Ministries) started several programs. First, it made grants for a few projects: research on various problems concerning clinical information disclosure, assigned to the Association of the Management of Medical Records, and seminars for disseminating the JMA's

guidelines among medical professionals, assigned to the JMA. (Some may find it anomalous that the JMA declares voluntary disclosure as the ethical duty of physicians on one hand, and receives from the government the subsidy to fulfill it on the other hand.) Second, it revised the public relations provision in the Medical Service Law and allowed medical institutions to advertise their readiness to offer clinical information, including medical records. Third, it added a new item in the medical fee schedule: medical records management fee. This was meant to reward medical institutions which have a medical records manager, maintain the satisfactory records and actually disclose clinical information to patients. The amount was surprisingly small, though, and it was obviously insufficient to cover the costs.

Ⅵ. Personal Information Protection Law in Japan

In 1980, OECD issued Guidelines on the Protection of Privacy and Transborder Flows of Personal Data which aim to harmonize two seemingly conflicting demands: privacy protection in the information technology age on one hand, and utmost utilization, domestic and international, of various pieces of information on the other. They included eight principles: Collection Limitation Principle, Data Quality Principle, Purpose Specification Principle, Use Limitation Principle, Security Safeguards Principle, Openness Principle, Individual Participation Principle, and Accountability Principle. OECD recommended its member countries to take measures to implement these principles in their domestic laws. [15]

In Japan, local governments started to lay down ordinances for personal information protection about the documents they have. As was seen in the second section, the disclosure of medical claims was conducted based on these ordinances. In 1988, the

national government enacted a law to protect personal information stored in the computers of the government. The personal data protection in private sectors was left to each Ministry which was to supervise activities in its jurisdiction.

In 1995, the European Union issued the so-called Data Protection Directive. [16] It was meant to unify the diverse legislations in its member states, but Article 4 asked any organization outside the EU territory doing business with EU companies or individuals also to maintain the same level of personal data protection. This prompted the Japanese business world to ask for legislation comparable to the EU standard. Also, around 1995 there were several incidents of theft and sale of massive personal data and these were widely reported. In 1999, the government started more seriously the preparation for the new personal information protection law. Basically the law was to implement the OECD guidelines. In 2003, the law and the specific laws for the governmental organizations were approved by the Diet. The core part of the law, including the individuals' participation clause, was to take effect two years later. The specific regulations for private sectors were to be carried out by additional laws and guidelines to be established, taking into account the characteristics of various activities. The government named medicine, finance and telecommunication as important areas of personal data protection.

Ⅶ. The Committee on the Way Clinical Information is to be Disclosed (the Omichi Committee of 2002), 2002 – 2003

The preparatory period was to end in 2002. The government's new deregulation program, in the area of medicine, asked to establish rules or guidelines for clinical information disclosure by 2002, in order to promote medical records disclosure. And more importantly, the government was

determined to enact the Personal Information Protection Law. Thus, the Ministry of Health, Labour and Welfare started a new committee to examine the way clinical information is disclosed to patients. Out of the nine members of this committee, six were from the field of medicine, two as representatives of the general public, and one from law. The chairperson was Mr. Omichi, professor in medicine and a board member of the Association of the Management of Medical Records. The complete transcripts of the meetings were made available online, in addition to the many reference materials used in the meetings. This committee submitted its final report in June 2003. [17]

This committee had two purposes: the evaluation of the way clinical information had been disclosed to patients during the preparatory period, and the drawing up of guidelines or some other rules to promote medical records disclosure. On the first point of evaluation, the final report, on one hand, notes the remarkable advances in disclosure during the last few years, referring to a number of empirical studies, but, on the other hand, points out that there are still a sizable number of medical institutions which are not ready to offer enough information to the patients, and also that much poor communication give rise to patients' distrust towards medicine in general.

On the second point of guidelines or rules, towards the end of the committee deliberations in the spring of 2003, the Personal Information Protection Law seemed almost certain to be approved in the Diet. Therefore, on the surface the committee discussed the possible rules for the disclosure from 2002, but what the members had in mind may be whether, after the full enactment of the law in 2005, to regulate the specific area of medicine by means of guidelines or by new legislation.

Several professional organizations expressed their view through their members in the committee. The Japan Medical Association and The Japan Dental Association were opposed to

the legislation. They emphasized that they were making efforts for disclosure with their own initiatives and added that legislation would not contribute to promote satisfactory disclosure. The All Japan Hospital Association was in favor of the basic law that lays down the principles in medicine but considered the specific law of disclosure as redundant. It had adopted and put into practice the policy of full-scale disclosure and regarded the enforcement by law would not promote further disclosure. Still, it was not necessarily opposed to the idea of legislation. The Nursing Association was in favor of the legislation.

The other members were in favor of the legislation, including a professor of social medicine. They argued that for those who now already disclosed, legislation would not be any stumbling block, and for those who were half-hearted, law would give a nice incentive. One member asked a representative of the JMA whether it is acceptable if the entire text of the present JMA guidelines becomes the law about disclosure without any slightest changes. The JMA representative's response was that the coercive nature inherent in the legislation would impinge on physicians' autonomy.

The committee managed to work out a compromise. During the period of 2003 through 2005, before the Personal Information Protection Law would be fully enacted, medical institutions are expected to follow the guidelines on disclosure sanctioned by this committee and, therefore, by the government. From 2005 onward, separate legislation on medical information disclosure would be considered only when there arise problems which could not be addressed by the guidelines, or otherwise the regulation would be carried out by the guidelines.

The final report of June 10, 2003 was written, with the Personal Information Protection Law in mind, which was approved by the Diet on May 23, 2003. The first point to note was

the reasons why the disclosure of clinical information was regarded as necessary. It cited the patient's right to self-determination and the patient's right to know, in addition to the creation of better trust relationships between patients and medical providers, the elevation of the quality of medicine by means of sharing clinical information. As we have seen, the first two reasons were intentionally left out in the JMA's guidelines. Some members wanted to place more emphasis on these, but the report went only as far as to mention those rights as the reasons "why the disclosure of clinical information is regarded (emphasis added) as necessary", not "why the disclosure of clinical information is necessary."

The second point is about the legal duty to disclose. The report notes that the recently approved Personal Information Protection Law covers the clinical information stored in the medical institutions whose personal data consists of more than 5,000 records. Therefore, such institutions have a legal duty to provide patients with their clinical information. In addition, many local governments have ordinances to protect personal information. Thus, most medical institutions are legally obliged to disclose clinical information, including medical records, to patients upon their request. In sum, the legal basis for disclosure has been established. The committee deliberated, the report goes on, on whether to establish a new law in the area of medicine. The members in favor argued that the new legislation will guarantee the patients' right to know, will make medical practices more transparent, and will help erase distrust towards medicine, and that because the Personal Information Protection Law protects the information related to living persons only, the disclosure of clinical information to the family members of a deceased patient must be secured by a separate law. On the other hand, other members argued that a further legislation is not necessary, and that the people who personally care most for the

patient are not necessarily the closest kin, and the law's provision, whatever it might be, may exclude them. The committee's conclusion was that the guidelines for the disclosure should be drawn up, first to cover the two-year period before the full enactment of the Personal Information Protection Law, and second to promote the disclosure on the part of small-scale medical institutions (whose personal data records are fewer than 5,000) and also to the family members of a deceased patient.

The draft of the guidelines was attached to the report itself. After receiving public comments and making necessary revisions, they were to become the official ones. The report added some comments to the draft of the guidelines. The first was that the draft allows two exceptions to disclosure: the possibility of harm to the patients, and that of harm to others, but the first possibility could be excluded and the so-called therapeutic discretion does not have to be exercised. This may be a reflection of the policy of The All Japan Hospital Association. The second was that even when the patient seems to have a lawsuit in mind, medical institutions are not supposed to refuse the disclosure simply because of the possibility of litigation. This is in line with the spirit of the Personal Information Protection Law, and also a clear rejection of the JMA guidelines, which says in the supplementary commentary that the guidelines are not applicable when a lawsuit is expected.

After the public input and some revisions, the draft became official guidelines of the Ministry of Health, Labour, and Welfare.[18] In 2004, the Ministry set up another committee, to discuss measures to protect personal information in the area of medicine and long-term care, before the full enactment of the Personal Information Protection Law in 2005. In December 2004, it issued the guidelines and also a Q&A to help providers and institutions understand what is expected of them.

Notes

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3 Ministry of Health and Welfare, "Questions and Answers on National Health Insurance," 1979. (Kosei-sho, Kokumin Kenko Hoken Shitsugi Oto Shu)
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6 The Mainichi Newspaper, 1996.01.27
7 The Asahi Newspaper, 1994.05.12, The Asahi Newspaper, 1995.11.28, The Mainichi Newspaper, 1996.06.28
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