Laws on Medicine

Lecture No.13 (in Classroom 22,on Wednesday, January 14, 2009, at 15:00-16:40)

Sequel to Chapter 7: Human Specimen and Legislation

1）What should our thoughts be as to human specimens of organs and cells?

2）How did the latest English law deal with this issue?

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What Human Specimen Is

"Ethical Guideline on Clinical Research" by Ministry of Health, Labour and Welfare on Jul. 30, 2003 (full-fledged revision on Dec. 28, 2004)

(3)Specimen and such

- Refer to the following intended for use in clinical research: blood, tissue, cell, body fluids, excrement, and part of human body such as DNA extracted from these, and medical information of test subjects (including ones related to dead persons)

"Tissues and Cells Extracted for Diagnosis; 70% of Hospitals Apply to Research Purpose Without Permission," Morning News of Asahi Shimbun Dated 11/13/02

Japanese Society of Pathology: "Opinion on the use of pathological specimens for academic researches and medical education"

"When the remainder of what is required for diagnosis out of a pathological specimen is utilized for the purpose of research/education for the sake of progress of medicine and medical treatment, it is desirable that an agreement in writing is obtained from the subject patient or his/her advocate (person with parental authority, relative). (an example sentence being attached)"

— Society of Pathology Bulletin, no.158 (Dec. 2000)

http://jspk.umin.jp/com_work/gyoumu/Kaiho.html

Page of "Opinion" of Morning News of Asahi Shimbun Dated 12/10/02

- Confusion at job site
- "Patients are supposed to be aware that, in a university hospital, while a state-of-the-art therapy can be expected on one side, they'll become research materials to a certain extent on the other side."
- It is possible that valuable case researches cannot be conducted. Is it good to progress of medicine?
- "It is hardly imaginable that a research brings about disadvantage to patients."
- "It is possible that a relationship of trust with patients breaks down."
- "It's questionable if patients, preoccupied with own therapy, will have an understanding."
- "Other than tissues, should an agreement be obtained for X-ray photographs, and blood and urine to be taken extensively?"
- Tsuyoshi Awaya, professor of bioethics at Okayama University: "The tissues collected originally belong to the patient. The handling should be discussed not just from an ethical aspect, but from a legal standpoint."

How It Should be Considered

1 Whom does a (human) specimen belong to?

Right-of-ownership approach

Need for a special treatment of what is originated from a human body

Personal-rights approach

2 Living body and dead body

3 Various human specimens: hair, blood, liver

4 Utilization purposes: research, education/ study training

Demand for Return of Specimen, and Case of Claim for Damages

A 67-year-old woman dies over the course of hospitalization; the name of the disease is scleroderma renal crisis. A doctor in charge requests of the patient's husband and son for a pathological dissection and the preservation of the internal organs and cerebrum, to which they consent.

Subsequent two lawsuits in which the son is the plaintiff :

①Suit to demand for the return of the specimens

②Claim for damages as to the collection of—without permission— and damaging a piece of prepared specimen of the hypophysis

Trials that Resulted in Different Decisions

Verdict of Tokyo District Court on Nov. 24, 2000; *Precedent News Reports no. 1738*, p.80

Verdict of Tokyo District Court on Aug. 30, 2002; *Precedent News Reports no. 1797*, p.68. Verdict of Tokyo Higher Court on Jan. 30, 2003 (not recorded in law reports, but introduced in detail in Yuichiro Sato, *Case of Unconsenting Preservation of Pathological Dissection Specimen,* Shin Utsugi=Saku Machino=Katsumasa Hirabayashi=Katsunori Kai, ed., *One Hundred Selected Precedents on Laws on Medicine*, pp.100-101, Yuhikaku, 2006)

Furthermore, although the bereaved family made a final appeal, it met the dismissal/nonacceptance, and was confirmed.

Why Results are Different

- Concept

  Relationship between the doctor and bereaved family: contract

  Donation contract/employment contract/bailment contract

  Established right on the bereaved family

  Breakdown of fair and equitable principles/fiduciary relation

- Concept/way of thinking are common.

  Only up to the evaluation of all the facts

Confusion at Job Site about Principle of Consent

①Patients are expected to know well that university hospitals are research and education institutions. Specimens that have been used for patients' diagnosis and are already useless to them.

②Explanation for the sake of a consent; possible to break down a relationship of trust with patients

③Human specimens include a variety of stuff. Is a written agreement necessary for taking a blood sample and urine collection to be conducted extensively?

Extra strain on the job site that is already busy; no merit to patients other than an additional time for waiting

Analysis of Issue

The question of utilization of pathological specimens for research and education involves two arguing points. Firstly, what a principle is to properly handle specimens originated from human bodies such as organs and cells. The second point is the multitiered nature of the utilization purpose that is not for diagnosis and treatment but for medical research and education, which, in other words, cannot help to put the doctor in a position of conflicting interests, constituting a difficult problem.

To Learn from American National Examination for Medical Practitioners

【Question 12】 A man had an accident and was carried into an emergency ward already attached to an artificial respirator, but was judged brain-dead by every criteria. In the wallet he had an organ donor card clearly expressing his intent of an organ transplant. The organ transplantation team made a contact with his family, who turned out to reject to agree on the transplant. What should be done about this?

【Question 20】 You have become a leading member of a research group to conduct clinical examinations for trying out efficacy of a new drug for heart disease, and are about to present the fruit in the form of a thesis. This research has been done with a huge amount of aid provided by a pharmaceutical company having the largest market share of this type of drugs. In the wake of publishing the thesis, what is the most appropriate factor from medical ethics viewpoint?

①Legislation ≠ Medical Ethics

Not just legally right

②Conflict of interests

Not treated as a simple prohibitive rule

U.K.'s Human Tissue Act 2004

Alder Hey Children's Hospital case in 1999

Human Tissue Act 2004

- Research use: dead body, living body

  But there's good practice.

- Training and development: dead body, living body

Veronica English (translation by Futoshi Iwata & Kei Niinuma), *U.K. 2004: Human Tissue Act and Its Influcence*, Norio Higuchi=Futoshi Iwata, ed./author, *Bioethics and Law II,* p.147 (Kobundo, 2007)

Suggestion from Three Data

①In the background of the use of pathological specimens for research and education lies a problem of conflict of interests.

②Being doubtful does not lead to a ban on the use for research and education. It isn't beneficial to patients either.

③A principle of consent is not the only way to make the use for research and education possible.

④Upon considering a rule, it is acceptable that a response by legislation is different from one by medical ethics.

Way to Make Rule

5 alternatives as to the use of pathological specimens

Same way as the rules on the use and protection of personal information
Higuchi, *Consideration of Medical Care and Law— Ambulance and Righteousness*, p.190

1) Free use rule
2) Disclosure rule—not consent, but disclosure
3) Opt out rule—though consent is necessary, if objected particularly, the use gets suspended .
4) Opt in rule—consent in advance
5) Prohibition rule—ban on the use despite consent

Easy Dependence on Principle of Consent

①Taking specimens for the purpose of clinical research and their usage: guideline by Ministry of Health, Labour and Welfare

②In case a research usage is planned at the time of taking specimens for diagnosis and treatment: guideline by Ministry of Health, Labour and Welfare

③Question is a case specimens, taken for the purpose of diagnosis and treatment, are used for research subsequently: outside the Ministry's guideline—(1) Medical practice for the purpose of diagnosis and treatment, "No.1 Basic Thought—2 Applicability Coverage" in "Ethical Guideline Regarding Clinical Research," Ministry of Health, Labour and Welfare, Jul. 30, 2003 (full-fledged revision on Dec. 28, 2004)

Opinions on Way of Thinking

1) Worst case patients are afraid of: tissues more than necessary might be taken for the research's sake. That's a crime (injurious assault).
2) Problem is the case of conflict of interests. For examination/ treatment to take important specimens of organs and tissues, a written consent should be obtained from the beginning. And which reads like, "While tissues taken are for the usage of diagnosis and treatment of patients, the remaining potions after such purposes are attained may be used in the future for the sake of medical research and education. Please be advised to understand this." Just for taking a blood sample, a disclosure by a simple notice on a bulletin board should do.
3) Nonetheless, the above does not apply those patients who object in particular .

★Taking specimens of tissues and such from dead bodies

The same rules may be applicable.

But a request for turnover from the bereaved family must be accepted based on Postmortem Conservation Act.

Bibliography

- Norio Higuchi, *Sequel to Consideration of Medical Care and Law — Medical-Care Guidelines for Terminal Phase of Disease,* chapter 7 (Yuhikaku, Nov. 2008)
- Chapter 3: Pathology in Society—2. Research Ethics, in *Pathology and Society*, extra number of '*Pathology and Clinical Care*' vol.27, Bunkodo