Laws on Medicine

Lecture No.12 (in Classroom 22, on Wednesday, December 17, 2008, at 15:00-16:40)

Sequel to Chapter 5: Guidelines for Terminal Care

１）What type of rules should it be to discontinue keeping a person alive?

２）What are the process guideline established at the national level for the first time?

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3rd Social Page of Morning News of Asahi Shimbun Dated 10/8/08

Reporter Shinoda in NHK News Program of 10/7/08

"No problem from an ethical standpoint" as to removing respirator from the patient of an intractable disease: Opinion of a hospital ethics committee in Chiba

The ethics-issue exploratory committee of Kameda General Hospital (director Nobusuke Kameda) located in Kamogawa-city, Chiba-pref. established an opinion that "there is no ethical problem" regarding a patient of amyotrophic lateral sclerosis (ALS) who makes a request to remove an artificial respirator when the patient becomes disabled to communicate with those around him. Removing a respirator from progressed cases of ALS might have a decisive impact on life. According to a self-help patient group, it is rare that a medical institution's ethics committee expresses an opinion on such a request of a case of ALS.

But the ethics committee does not make a definite statement as to how to respond to the request as "there is a possibility of criminal prosecution against any personnel who has removed respiratory apparatus."

This patient is a male (68) from the same prefecture, who was diagnosed with an intractable disease ALS in 1991, and the following year got into respiratory difficulties requiring tracheotomy and wearing a respiratory apparatus. While bedridden, he communicates with his family by writing sentences with PC by the use of his right cheek that can move a few millimeters.

According to the family, this man considers that he "lives a human life only while there are communications with the family, friends, and medical staff," and wishes to "have a respirator removed" when he becomes incapable to do that.

NHK news reported: "Discussion and research are necessary," and "no law approves the removal of respiratory apparatus ," and Prof. Itakura's opinion of " a possibility of the equivalent of murder by contract ."

Example from Case Book of U.S.

Furrow, et.al., Bioethics 1-5 (5th ed. West 2004)

"At 4:30 p.m. on a certain Friday, there was an incoming call to you being a legal advisor to a 300-bed hospital. The call was from Dr. Smith looking for your advice. This doctor examined a 37-year-old patient named Johns who was in the terminal stage of lung cancer that was already metastasizing to the bones. The status quo was that the remnant of his life was one month at best, and that the treatment was wholly focused on chemotherapy to delay disease progression and on an easing of throbbing pain. Besides, Johns had a pacemaker implanted.

Well, Johns said to the doctor to please discontinue chemotherapy and bring the pacemaker to an end. The same request was made repeatedly, and it was the doctor's judgment that the patient expressed his consistent intent under the clear consciousness. Accordingly, the doctor made a consultation as to what he should do."

→***No account of link to murder by contract!***

Importance of Process and Whereabouts of Problem

○"Notice of cancer to a patient's family—verdict in 3rd Petty Bench of Supreme Court dated Sep. 24, 2002" (Case in which a doctor was alleged to have violated the duty appended to medical care contract; where the doctor, based on the decision not to inform the patient of terminal cancer, did not notify the patient's family of the state of the disease)

Shinya Utsugi, ed./op., *One Hundred Selected Precedents on Laws on Medicine*, pp.120-121, Yuhikaku, 2006

At a hospital in Akita-prefecture…

1 Significance of the Supreme Court verdict

2 Point at issue

Dot and Line

1) Argument over dot
Whether or not the doctor should notify the patient or family of terminal cancer. A notice is a dot. More important is a system after the notice, without which notifying and not notifying are the same. But the jurist only focuses on the dot.

2) Argument over line
What sort of time (way of spending the period of the terminal stage) can be provided to a patient facing the closing period. The point at issue is not if the doctor notified, but if subject medical institution was equipped with a system to support a terminally ill patient. The problem is not an individual's error, but is one of an organization, one of a system.

Terminal Stage and Role of Law

Major Cases after Yokohama Local Court's Decision in 1995

1) 1996 case in which the director of Kokuho Keihoku Hospital in Kyoto put a patient with terminal cancer on a muscle relaxant drip: in the following year, it resulted in a disposition not to institute a public action on the ground that the applied dose was sublethal.

2) Kawasaki Kyodo Hospital in 1998: with a patient in a vegetative state under bronchial asthma, a doctor in charge right in front of the family took out intratracheal tube, and further, put on a muscle relaxant drip, only to let the patient die. The doctor was arrested in 2002 on suspicion of murder, sentenced to 3 years (with a 5-year suspension) at Yokohama Local Court in 2005. Tokyo Higher Court sustained the judgment of "guilty“ in 2007, but reduced the penalty to an imprisonment of a year and half (with a 3-year suspension) on the ground that there might have been a request from the family, identifying as the offense, not just the administration of muscle relaxant, but also the act of taking out the intratracheal tube. Still this case is being appealed to the Supreme Court.

3) Hokkaido Prefectural Haboro Hospital in 2004: the case, in which a male patient (90 years old then) was removed of an artificial respirator and brought to death, was committed for trial in 2006. It was dropped due to the difficulty in establishing cause-and-effect relation.

4) Imizu City Hospital in Toyama in 2006: a chief surgeon became the subject of the police investigation on a charge of having removed artificial respirators from multiple patients. There had not been to date a case of prosecution for, so to speak, single-minded interruption a life-sustaining treatment, without involving an administration of muscle relaxant.

Later, it was reported that the prefectural police sent the case to the district public prosecutors office with a recommendation “not to seek strict punishment.” (Asahi Shimbun dated Jul. 24, 2008)

5) Prefectural Tajimi Hospital in Tajimi-city, Gifu-prefecture in 2007: a case in which, despite the patient’s declaration of intent in writing and the decision of an ethics committee, as the hospital’s director had a contrary opinion, no action was taken to interrupt a life-sustaining treatment before the patient died.

6) In 2007 at Wakayama Prefectural Medical Hospital, criminal papers were filed with prosecutors against a doctor, who removed an artificial respirator, on suspicion of murder . The police sent the papers with an opinion , in pursuance of the family’s wish, not to seek a criminal punishment

History

1987 Investigative commission by Ministry of Health, Labour and Welfare, and one in every 5 years since

1993 Investigative commission on the national attitude survey regarding terminal care (Chaired by Tadao Kakizoe)

1994 Special Committees on Death and Medical Care by Science Council of Japan declares its opinion "about death with dignity" on May 26, 1994

1995 Yokohama Local Court's verdict on Tokai University Hospital's case

1997 Investigative commission on the national attitude survey regarding terminal care (Chaired by Keiichi Suemasu)

2002 Investigative commission on a survey, etc. regarding terminal care (Chaired by Saku Machino)

2006 Coverage of Imizu City Hospital case

Feb. 2007 Higher Court's decision on Kawasaki Kyodo Hospital case (reduced the probation by half, and emphasized needs for guideline and legislation)

May 2007 First guideline by Ministry of Health, Labour and Welfare

Guideline on Decision Process for Terminal Care

Process vs. substance

Imizu Hospital case→Not to make a decision by oneself
  Promise made by the then Minister of Health, Labour and Welfare
  Emphasized in the wake of the verdict on Kawasaki Kyodo Hospital case
Media coverage of Tajimi Hospital in Gifu-prefecture in Jan. 2007: “in a situation where no state guideline…”

Issue a guideline.
But, with caution.

Process Guideline

Contents in 3 points

1 Medical care team
2 Thorough rationalism
Respect for an intention of the person oneself, and further, of the family
3 Need for serious consideration and enhancement of relief care

Expectations and Misgivings about Guideline

Questions from different positions about the course of action centering on the process

1 Argument that it is only confusing to job sites, thus meaningless, so long as it is unclear what is to be held legally responsible (criminal responsibility, in particular), what is not to be held legally responsible

→Doctors/hospital associations

2 Uneasiness/misgivings that fulfilling the process would permit anything (possibly to force the patient to death)

→ALS patients' association, etc.

Text of Guideline

1 What terminal care should be

①The most important principle for terminal care to be proceeded with is that an appropriate information and explanation are provided by the medical worker like a doctor, upon which the patient holds a consultation with said medical worker and makes the decision himself.

Note 1: For the sake of better terminal care, firstly, the patient's decision after obtaining an adequate information and explanation is quite important. Needless to mention, however, it is required that medical appropriateness and relevance are guaranteed as terminal care, to be stated in ②.

Text of Guideline

②In terminal care, regarding a start/non-start of medical practice, a change of contents of medical treatment, an interruption of medical practice, the judgments on these ought to be made cautiously by a medical care team comprised of medical workers in specialist kind of jobs on the basis of medical appropriateness and relevance.

*Note 2: There are a variety of ranges of the terminal stage; a case in which, like the terminal stages of cancer, a prognosis can be estimated to be a few days to 2-3 months at most, a case in which a chronic disease repeats acute exacerbation, lapsing into an unfavorable prognosis, and a case in which it takes a few months to a few years to approach death as in an aftereffect of cerebrovascular disease or infirmity of old age. To identify what sort of status is the terminal stage ought to be the matter of a relevant and appropriate decision by a medical care team based on the patient's situation. Additionally, in the event of emergency when there is no time for forming a team, a doctor cannot help but make his decision on the ground of respect for human life in principle, and of medical appropriateness and relevance; later, a medical care team is afresh to examine an appropriate medical treatment thereafter.

Text of Guideline

*Note 3: What a medical care team is like can be different depending on medical institutions' sizes and the number of people; in general, a doctor in charge, nurses, and other medical workers constitute a fundamental form. And, as in Note 6 mentioned later, when, for example, a social worker joins the team, while this personnel doesn't directly provide medical service, it is used in a sense to be able to be included in medical workers.

*Note 4: Two qualms are assumed about a medical care team. **One is a concern that it would be merely a confirmation of the superior thought of a doctor, and another that, vice versa, it would make ambiguous where the responsibility lies.** However, as for the former, in the wake of changes in the way collaborative relationships among medical workers should be, the reality ought to be rather emphasized in that medical workers other than the doctor are acknowledged making contributions as specialists in their individual fields. With respect to the latter, it is advised to be understood that this guideline is intended only to support the formation of a team designed for paying close attention to patients in the terminal stage from a medical standpoint, as well as to establish a system where each individual as a specialist offers a helping hand in cooperation. In particular, regarding legal aspects such as the way criminal liability and legal responsibility among medical workers should be, it is necessary to be examined continuously.

Text of Guideline

③It is necessary for a medical care team to ease a throbbing pain and other unpleasant symptoms as fully as possible, and practice an over-all medical treatment and care including mental and social assistance to the patient and family.

*Note 5: In light of the importance of palliative care, Ministry of Health, Labour and Welfare implemented in February 2007 a measure to ease the approval of a narcotic use for palliative care.

*Note 6: In approaching death, a person faces not only the need for pain control but also other kind of mental and social problems. It is hoped, if possible, that some personnel like a social worker, who gives thoughtful attention to social aspects, participates in a medical care team.

Text of Guideline

③This guideline does not target at active euthanasia intended to shorten life.

*Note 7: Unbearable pain accompanying a disease is an issue that should be resolved with palliative care. It is considered that there are some cases where active euthanasia is approved under extremely limited conditions according to the precedents and such. But as it is said that its prerequisite is unbearable physical pain, this guideline takes the position to state that, by emphasizing the importance of the care to ease physical pain, nothing is more important than further enhancing palliative care from medical standpoint. For this reason, it is not the objective of this guideline to clarify the issues as to what active euthanasia is, and what requisites are, with which it becomes legitimate .

Text of Guideline

2 Decision proceedings for terminal care and its method of treatment

Decision on terminal care and its course of treatment is to be as follows:

(1) Case in which the patient’s intention can be confirmed

①Grounded in a specialized medical study, the foundation is the patient’s decision making on the basis of an informed consent, and the practice gets done by a medical care team comprised of medical workers in specialist kind of jobs.

②At the time of deciding on a course of treatment, the patient and medical workers are to encompass discussion to the fullest, the patient is to make a decision, and the terms of the agreement are to be outlined in writing. In this case, in keeping with the lapse of time, changes in the state of a disease, and modifications of medical evaluation, as well as paying attention to the patient’s intention which is changeable, it is necessary to provide the patient with an explanation for each and every step so as to reconfirm the intention of the patient.

③In this process, it is advisable that the contents of the decision be informed to the family, unless the patient directs otherwise.

Text of Guideline

(2) Case in which the patient's intention cannot be confirmed

When the patient's intention cannot be confirmed, it is necessary that a careful judgment is made in a medical care team in accordance with the following procedure:

①If the family is capable to presume the patient's intention, the basics are to respect this presumed intention and to adopt a treatment plan that's best to the patient.

②If the family is incapable to presume the patient's intention, the basics are to fully discuss with the family what is the best to the patient and to adopt a treatment plan that's best to the patient.

③If there is no family or the family entrusts the judgment to a medical care team, the basics are to adopt a treatment plan that's best to the patient.

Text of Guideline

(3) Establishment of a committee comprised of multiple specialists
In those cases mentioned in (1) and (2) in the above, at the time of deciding on a course of treatment, it is necessary to separately establish a committee comprised of multiple specialists, which is to examine and advise regarding a course of treatment on the occasion of the following situations:

- When a decision on contents of medical treatment is difficult in a medical care team because of a morbid state and such;
- When an agreement cannot be reached in a discussion between the patient and medical workers as to appropriate and relevant contents of medical treatment;
- When an agreement cannot be found in the family, or in a discussion with medical workers, an agreement cannot be reached as to appropriate and relevant contents of medical treatment.

*Note 13: A committee to be established separately is exceptionally required only when an agreement cannot be reached among the patient, family, and a medical care team even after the process aimed at a sound terminal care. After examinations and advices there, it is necessary for these parties concerned to strive again for a consensus building by means of improving care methods, etc.

Subsequent Actions

1 Draft outline by "Federation of Congresspersons Considering to Legislate Death with Dignity" in June 2007
2 Japanese Association for Acute Medicine guideline in November
http://www.jaam.jp/html/info/info-20071116.htm
3 "About the way terminal care should be," the report in February 2008 by the terminal care subcommittee of the clinical medicine committee of Science Council of Japan
4 Commission of Imizu City Hospital case for trial in July (not to seek for a severe punishment)
5 NHK coverage of the patient in Chiba in October
6 Commencement of a friendly meeting on the way terminal care should be, in October
http://www.mhlw.go.jp/shingi/2008/10/s1027-12.html (#3 in the above being attached as data)

Draft Outline of Bill on Discontinuation of Life-sustaining Medical Treatment

Announcement of the draft outline by "Federation of Congresspersons Considering to Legislate Death with Dignity" in June 2007

◇Essence of the draft outline

(Definition)

･Near-death state is the one where there is no possibility of recovery even with all proper treatment and also nearing death.

･Life-sustaining measures are the ones not with the purpose of treating a patient but just to sustain his/her life (including the supply of nutrition and water).

(Discontinuation of life-sustaining measures)

･A doctor is permitted to discontinue life-sustaining measures when there is a manifestation of the intent by a patient (of 15 years old and elder) which the family does not deny.

･Near-death state is judged by two or more doctors.

(Punishment)

･Fine up to ¥500,000 when a document on the judgment of a near-death state is not prepared or a false document is drawn up.

Comparison with Process Guideline

1)Overlap each other in the point that the intent of those who do not wish for life-sustaining measures is respected, and that proceedings are set up regarding the discontinuation of life-sustaining measures for those in terminal stages to be able to face death with dignity.

2)Different in the point as to the ways of drawing up the document, involvement of multiple doctors, and rule on immunity from responsibility thereof.

3)Strong patient, weak patient, dot and line

4)Treatment of documents

●This outline emphasizes proceedings for the discontinuation of life-sustaining measures, and centers on a theory of legal responsibility.

●Conversely, there is likelihood that legal responsibility may be questioned outside this.

Two Guidelines

Variety of terminal stages
- Terminal stage of a cancer patient
- Terminal stage in an emergency ward
- Terminal stage for the elderly

The report by Science Council and the guideline by Association for Acute Medicine respond to the first two of the above.

Both seek for a decision fulfilling the process.

In Lieu of Conclusion

Case of removing an artificial respirator in Wakayama May 2007
Commission for a trial with the recommendation not to seek a criminal punishment

Threat of criminal justice→Obstruction of an original inclination of medical personnel
Question of how to die and how to live depends not on legislation but on what medical ethics and an individual's awareness of the issues (which are changeable) should be.

In substance, is it not adequate to issue a declaration or guiding principle intended to state, "when it is made clear that a process has been taken to respect the intention of a patient in person after the orderly steps, it is considered that there is no need for criminal justice to intervene"?

Bibliography

- Norio Higuchi
- *Sequel to Consideration of Medical Care and Law — Medical-Care Guidelines for Terminal Phase of Disease,* chapter 5
- (Yuhikaku, Nov. 2008)